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EU Pharma Package: a new approach to platform technologies and combination products?

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1. Introduction

Abreu Advogados is today publishing the first in a series of analyses of the European Union's pharma package. Over the coming weeks, we will present our analysis of the proposed new Medicines Directive and the new Regulation, which are currently in the final stages of the legislative process.

These legislative acts represent the most significant overhaul of the EU's medicines regulatory framework in recent decades. They seek to address a range of structural challenges facing the sector, from access to innovative medicines and the availability of essential medicines, to the sustainability of healthcare systems and the competitiveness of the European pharmaceutical industry in the global context.

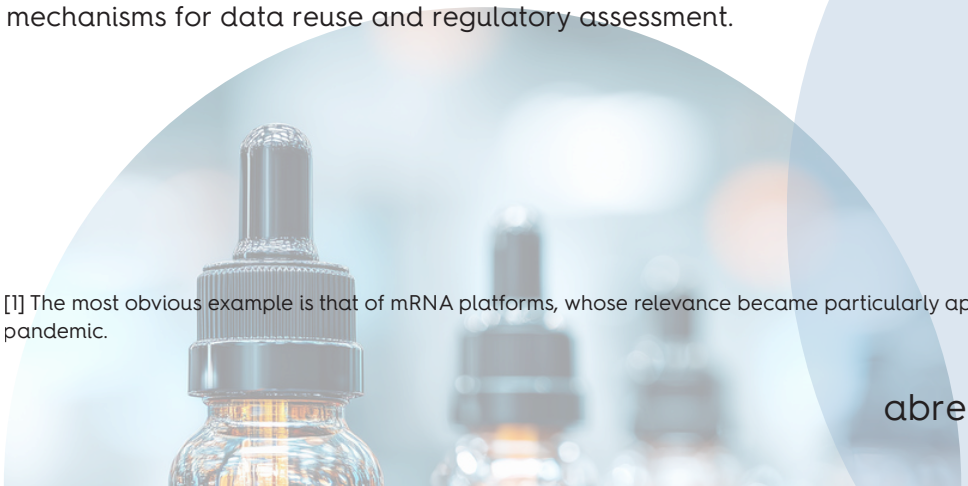
The proposed changes cover a wide range of issues, including incentives for innovation, regulatory and intellectual property protection, marketing authorisation procedures, the regime for orphan and paediatric medicines, and the strengthening of the role of national regulatory authorities and the EMA. The new legislative package will impact regulators, companies, healthcare providers and citizens.

Throughout this series, our Health, Life Sciences and Pharmaceuticals team will analyse the key developments and their practical implications, contributing to a better understanding of a legislative process that will shape the sector for years to come.

2. Platform Technologies: a new approach to regulatory assessment

In 2020, the development, assessment and authorisation of COVID-19 vaccines within an exceptionally short timeframe marked a turning point for biomedical innovation. More than just an isolated case of responding to a public health emergency, this process highlighted an issue that the pharmaceutical industry and regulators had already identified: the need to ensure that the European regulatory framework is equipped to keep pace with biomedical innovation in a systematic and sustainable manner.

Platform technologies are technological systems that enable the development of a variety of medicines or therapeutic variants from a common basis.[1]Their value lies not only in the final product, but also in the underlying platform, raising questions regarding the reuse of data, the scope of prior assessment and the degree of flexibility permissible in subsequent authorisations. Although the concept of a platform is not new, the pharma package recognises that the evaluation of medicines based on the same technological platform may justify specific mechanisms for data reuse and regulatory assessment.



[1] The most obvious example is that of mRNA platforms, whose relevance became particularly apparent during the COVID-19 pandemic.

A. Platform Technology Master File: data reuse and regulatory efficiency

One of the central instruments of the proposal is the Platform Technology Master File ("PTMF"), designed to allow data already assessed on a given platform technology to be reused in subsequent marketing authorisation applications ("MAAs").

The aim is to ensure that, once the platform has been characterised and assessed, the regulatory review of future medicines can focus on product-specific elements, thereby avoiding duplication, optimising resources and providing greater predictability for market operators. Thus, an applicant for a marketing authorisation may rely on a PTMF certified by the European Medicines Agency ("EMA"), rather than resubmitting all data relating to the platform technology.

Certification will depend on a positive assessment and confirmation of eligibility by the EMA, which will maintain a repository of certified PTMFs, accessible to national authorities, whilst safeguarding the protection of personal data and confidential information.

However, platform technologies may remain subject to inspection, and failure to comply with applicable obligations may lead to the suspension or withdrawal of certification, with possible consequential effects on the marketing authorisations that depend on it.

B. Platform Technology Marketing Authorisation: flexibility for medicines with variable components

In addition, the proposal introduces the Platform Technology Marketing Authorisation ("PTMA"), applicable in exceptional circumstances, intended for medicinal products with a fixed component and a predefined variable component, allowing the product to be adapted to different variants of an infectious agent or to the characteristics of an individual patient or a group of patients, thus constituting an authorisation mechanism geared towards medicinal products whose configuration allows for the updating of the variable component. The use of this mechanism requires the prior agreement of the competent authority regarding the submission of the application.

3. Combination products: the interface between medicines and medical devices

The second category relevant to operators is that of combination products, in particular those which incorporate both a medicinal product and a medical device.

These products pose an added challenge, as in practice they cover situations where the safe and effective use of the medicinal product will depend on its interaction with a medical device or another technological component - such as medicinal products associated with diagnostic or monitoring devices. In such cases, the conformity assessment of these combination products must cover not only the active substance, but also the method of administration, the performance of the device and the interaction between components.

The proposal therefore seeks to clarify the framework applicable to these combinations, distinguishing between integral combinations, medicinal products intended for exclusive use with medical devices, and combinations with products other than medical devices, with differentiated requirements depending on the degree of integration between the components.

In practical terms, the proposal aims to make the interaction between different regulatory regimes more predictable, clarifying which elements must be considered when the medicinal product relies on a medical device or another technological component.

For market operators, this will mean taking the hybrid nature of the products into account from the development phase onwards, so that the marketing authorisation application reflects, from the outset, the interaction between the medicinal product, the device and clinical use - a coordination that must be ensured throughout the assessment process and across the entire life cycle of the product.

4. Practical implications for market operators

Although the legislative process has yet to be concluded, the pharma package provides a clear direction in this regard: to adapt the European pharmaceutical framework to products whose technological complexity extends beyond the individual assessment of a medicinal product.

In the case of platform technologies, the proposal seeks to address the need to reuse previously assessed knowledge and data, without removing the requirement to demonstrate the quality, safety and efficacy of the specific medicinal product. In the case of combination products, the proposal points towards a more predictable interface between the medicines regime and that of medical devices, recognising that, in certain cases, the appropriate use of the medicinal product depends on its interaction with other technological components.

This development does not necessarily imply a reduction in the regulatory burden. On the contrary, it may require greater technical, documentary and organisational preparation on the part of operators. The main change appears to lie in the way this requirement is structured: less focused on rigid categories and more oriented towards the functional reality of the product.

In conclusion, it will be essential to monitor the development of the final text and assess how these solutions may impact the business strategies of operators in the sector.

Thinking about tomorrow? Let's talk today.

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