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Transforming Europe's pharmaceutical future: the EU Pharma Package and its comprehensive reform

The European pharmaceutical sector is undergoing its most significant reform in over two decades with the introduction of a comprehensive reform (the "**EU Pharma Package**"). Presented by the EU Commission in April 2023, this initiative represents the first major overhaul of EU pharmaceutical law since 2004, aiming to replace the existing framework with a new Directive and a new Regulation. The reform will also consolidate rules relating to orphan and paediatric medicines (Regulations 141/2000 and 1901/2006).

The objectives of the EU Pharma Package are threefold:

> To improve patient access to medicines,
> To strengthen the EU's global competitiveness, and
> To promote innovation within the pharmaceutical sector.

In April 2024, the EU Parliament adopted its position, toning down certain elements of the EU Commission's proposal. The EU Council later adopted its negotiating mandate, and finalised its stance on 4 June 2025. With all three institutions, the EU Commission, the EU Parliament and the EU Council, now aligned on their positions, trilogue negotiations are under way to agree on the final texts.

A political agreement between the three EU Institutions mentioned above is expected by the end of 2025, with the reforms entering into force 20 days after publication in the Official Journal of the EU. In this context, the EU Council has proposed a 36-month transition period (longer than the 18 months initially proposed by the Commission).

The Bolar exemption in the EU Pharma Package: balancing patent protection and market access in the pharmaceutical sector

Following up on the previous paragraph ("***Transforming Europe's pharmaceutical future: the EU Pharma Package and its comprehensive reform***"), with regards to intellectual property, among the many aspects of the EU Pharma Package, the Bolar exemption stands out as a key change with significant implications for both originator and manufacturers of generic medicinal products.

Introduced at EU level in 2004 by Directive 2004/27/EC, the Bolar exemption provides a legal safeguard against patent infringement for activities conducted to obtain a marketing authorisation ("**MA**"). In practice, it permits clinical trials and related activities for generic or biosimilar products while a patent or supplementary protection certificate ("**SPC**") is still in force. However, implementation across Member States has varied, leading to divergent interpretations and legal uncertainty.

The EU Pharma Package seeks to harmonise this framework. Under Article 85 of the proposed Directive of the EU Pharma Package, the exemption is expanded to cover activities undertaken exclusively for:

> MA applications for generics, biosimilars, hybrids, or bio-hybrids (and subsequent variations);
> Health technology assessments (as defined in Regulation (EU) 2021/2282); and
> Pricing and reimbursement procedures.

The exemption expressly excludes the placing of products on the market before patent expiry. It now also covers a wide range of preparatory activities - including manufacturing, import, supply, and storage - extending to third-party suppliers and service providers.

Institutional positions differ:

> The EU Parliament broadened the scope by removing references to specific product categories, potentially extending the exemption to innovative medicines, and clarified that it applies to MA applications outside the EU;
> The EU Council reinstated stricter focus on generics and biosimilars, but extended the exemption to include procurement activities (e.g. participation in public tenders), again excluding premature marketing.

In Italy, the Bolar exemption is implemented under Article 68 of the Industrial Property Code and the Italian Supreme Court clarified its limits in judgement No. 18372 of 5 July 2024. In particular:

- Activities must be strictly necessary for obtaining an MA; promotional or commercial activities remain outside the exemption and may constitute infringement;
- For companies manufacturing active ingredients on behalf of third parties, the exemption applies only where production is limited to MA purposes and does not amount to commercial exploitation;
- Clear contractual arrangements between pharmaceutical companies and contractors are essential to avoid disputes, ensuring that the destination of the product is solely linked to post-expiry marketing.

In conclusion, the reform of the Bolar exemption under the EU Pharma Package aims to:

- Harmonise divergent national practices;
- Reduce regulatory uncertainty; and
- Create a level playing field across the EU.

For manufacturers of generic and biosimilar medicinal products, the changes provide legal certainty that preparatory regulatory activities do not constitute an infringement. For originator companies, they offer a more predictable framework for managing exclusivity.

Ultimately, the reforms seek to balance two core policy goals: from safeguarding intellectual property to incentivise innovation, while ensuring prompt access to affordable medicines for patients and healthcare systems. This balance will shape the strategic choices of both innovators and generics, and will significantly influence the future of Europe's pharmaceutical landscape.

Healthcare professionals' liabilities: the Italian Council of Ministers has approved a new bill that shapes the professional liabilities of healthcare professionals

On 4 September 2025, the Italian Council of Ministers approved the bill (called "delegation of powers to the Government regarding healthcare professions and provisions relating to the professional liability of healthcare professionals" - *delega al Governo in materia di professioni sanitarie e disposizioni relative alla responsabilità professionale degli esercenti le professioni sanitarie*) which aims, *inter alia*, at providing for a new regime to safeguard healthcare professionals in the event of professional liabilities.

In particular, the bill (Article 7) focuses on the criminal liability of healthcare professionals by removing the culpability of healthcare professionals for manslaughter (*omicidio colposo*) and negligent personal injury (*lesion colpose*) offences committed in the healthcare sector, provided that the following circumstances occur:

> The offences are not caused by gross negligence of the healthcare professional;
> The healthcare professionals' conduct is compliant with guidelines and good clinical practices, provided that they are appropriate and applied to the specific case, as required by law.

Furthermore, Article 7 of the bill introduces a specific article in the Italian Criminal Code relating to negligence in healthcare activities, in order to identify specific parameters on the basis of which the judge assesses negligence (e.g., the shortage of available human and material resources; organisational shortcomings; complexity of the patient's condition).

The measures mentioned above aim at balancing the necessary protection of victims of medical errors with the protection of healthcare professionals from excessive criminal liability for minor or unavoidable errors, especially in cases of limited resources or complex clinical situations.

The bill is now expected to be examined by the Italian Parliament before becoming law.

Personal data: the judgment of the EU Court of Justice in the case C-413/23P of 4 September 2025 forces a rethink of personal data and transparency (EDPS v. SRB)

On 4 September 2025, the EU Court of Justice issued a judgement that could impact on the current regime regulating personal data. The case revolved around the Single Resolution Board's ("**SRB**") transmission of pseudonymised comments from its shareholders and creditors to Deloitte, as part of a resolution process involving Banco Popular Español, S.A.. The European Data Protection Supervisor ("**EDPS**") argued that these comments were personal data and that SRB had failed to inform the individuals that their data would be shared with third parties.

The Court introduced a nuanced view: if the recipient (Deloitte) cannot reasonably re-identify the individuals, the data may be considered as not personal from the recipient's perspective. This "relative" concept of personal data - *i.e.*, that the nature of personal data depends on an actual analysis of the means reasonably available to the data recipient to re-identify information which is encoded or pseudonymised - challenges the traditional "absolute" view held by many regulators. Crucially, this interpretation creates a powerful incentive: in order to place transferred data outside the scope of the GDPR, both sending and receiving organisations may increasingly seek to pseudonymise data as thoroughly as possible and ensure that recipients are not structurally able to re-identify individuals.

Some questions may arise from the above scenario: if pseudonymised data is not personal for the recipient, should the latter still be bound by privacy obligations? Does the party sharing such data need to inform individuals about recipients who cannot identify them, or is it an unnecessary compliance requirement?

In the case at hand, the answer of the Court is clear: **the duty to inform lies with the first data controller** (*i.e.*, SRB), **and it must be fulfilled at the moment of data collection - not later, and regardless of the recipient's ability to identify the data subject**. The information obligation is part of the relationship between the data subject and the first controller: even if the data becomes non-personal for the recipient after pseudonymisation, the controller must still disclose the recipient's identity at the time of collection.

However, the question remains unclear whether naming recipients who cannot actually identify the data subjects (such as Deloitte) truly improves individual protection: indeed, the recipient can always claim that it does not process personal data, whilst the data subject insists otherwise, relying on the information provided by the data controller's information policy. However, since the recipient has no means of identification, they are also unable to determine which data refers to whom. This paradox highlights a tension between formal transparency obligations and their actual utility in protecting individuals.

Data flows between the EU and the US: the EU General Court confirms the validity of the EU Commission's adequacy decision concerning data transfers from the EU to the US (Latombe v. EU Commission)

On 3 September 2025, by means of judgement issued in the case Latombe v. EU Commission (T-553/23), the EU General Court (the EU's second most important Court) confirmed the validity of the EU Commission's 2023 adequacy decision for the transfer of personal data from the EU to the US.

Under the EU General Data Protection Regulation (GDPR), the EU Commission can issue adequacy decisions allowing data, including personal health data, to be transferred from the EU to a non-EU Country without additional security measures such as standard contractual clauses or binding corporate rules. In 2023, the EU Commission issued the adequacy decision 2023/1795 (the "**EU-US Adequacy Decision**") declaring the adequate level of protection of personal data under the EU-US data privacy framework.

Mr Latombe (a French citizen) challenged the EU-US Adequacy Decision arguing, *inter alia*, that the US executive orders forming the basis for the 2023 Decision provided insufficient independent judicial oversight, allowed excessive collection of data by surveillance authorities and did not comply with EU standards on data security and automated decision-making.

The General Court dismissed each of Mr Latombe's arguments, finding, among other things, that, *(i)* the US Data Protection Review Court (DPRC) provided sufficient judicial oversight of US data collection, *(ii)* US law contained adequate limitations on bulk surveillance, and *(iii)* US law contained substantially equivalent safeguards in relation to data security and automated decision making.

That being said, the judgement in the Latombe v. EU Commission case could be challenged before the EU Court of Justice and it may lead to the annulment of the EU-US Adequacy Decision.

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