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1. Pharma Payback Under Constitutional Scrutiny: Italy's TAR Lazio Refers the “Endless Levy” to the Constitutional Court

With Order No. 12115 of 2 July 2026, TAR Lazio referred to the Constitutional Court the rules on pharmaceutical payback for direct purchases, questioning the legitimacy of Article 1(580) of Law No. 145/2018 and Article 15(7) of Decree-Law No. 95/2012 under Articles 3, 23, 41 and 117 of the Constitution. The claimants argued that insufficient statutory funding causes persistent overspending and an ever-increasing payback charge, making the mechanism unreasonable and disproportionate.

Moving from prior case law regarding payback on medical devices and innovative medicines, TAR Lazio **confirmed** that the **payback** is a **“solidarity contribution”, lawful under Article 23 only if temporary**; since it has applied since 2013 and been “stabilized” since 2019, it may have become structural and lost that rationale.

The Court **also doubted the mechanism’s reasonableness and proportionality, given its unpredictable annual amount**, continuous operation and poor fit with a procurement market increasingly based on freely negotiated prices, potentially restricting economic freedom under Article 41.

It further held that sums owed to pharmaceutical companies for directly distributed medicines qualify as a “possession” under Article 1, Protocol No. 1 ECHR, and may not meet the requirement of lawful interference with property under Article 117 of the Constitution.

The Order is also **significant for the medical device payback**, as it signals that any future extension or *de facto* stabilisation of similar mechanisms beyond a genuinely temporary framework could face the same constitutional challenge.

2. EU Pharma Reform Clears the Council: Countdown to a New Pharmaceutical Rulebook

On 28 September 2026, the Council of the EU formally adopted its first-reading position on the pharma package, a set of rules that will replace Directive 2001/83/EC and Regulation (EC) No 726/2004, confirming the political agreement reached with the European Parliament on 11 December 2025. This is the most significant overhaul of EU pharmaceutical legislation in over two decades, first proposed by the Commission in April 2023. Amongst the **key points of the reform**:

- **Regulatory data protection and market protection:** The current 8-year data protection period is retained, while the 2-year market protection period is reduced to 1 year, with up to two further conditional years available (for unmet medical need, multi-country comparative trials, or a significant new therapeutic indication). Combined protection is capped at 11 years.
- **Orphan medicines:** The standard 10-year market exclusivity falls to 9 years, but a new “breakthrough orphan drug” category (addressing conditions with no existing EU treatment) receives 11 years.
- **Availability and shortages:** Member States retain the power (Article 56a/59) to require marketing authorisation holders to supply enough domestically, with safeguards against use for parallel trade; mandatory 6-month advance notification will apply to anticipated shortages.
- **Generics and biosimilars:** The Bolar exemption is broadened to let generic manufacturers conduct trials and participate in procurement tenders before patent or SPC expiry, supporting day-one market entry.
- **Faster procedures:** The standard EMA marketing authorisation review timeline is shortened from 210 to 180 days.

The text now passes back to the **European Parliament** for the final vote at second reading (expected by late autumn 2026) to definitively conclude the legislative procedure prior to publication in the Official Journal of the EU. The new rules will enter into force 20 days after publication, triggering agreed transitional periods. Full applicability is expected by 2028.

3. Healthcare Under ANAC's Spotlight: Corruption Risks and Prevention Measures under Recent Resolution No. 318/2026

With Resolution No. 318 of 29 July 2026, the National Anti-Corruption Authority ("**ANAC**") approved the new "Catalogue of Corruption Risks and Preventive Measures in the Healthcare Sector" (the "**Catalogue**"), primarily to guide NHS entities but with practical relevance for pharma operators dealing with the public sector. Among the most significant topics addressed in the Catalogue are:

- **Biomedical research:** ANAC identifies specific risks at different stages of clinical trials including research funds and conflict of interest between industry and physicians or researchers. Key safeguards include **transparent allocation criteria, publication of expenditure data, strengthened internal controls**, annual declaration of industry interests, **sharing raw data** and ensuring that payments reflect fair market value and are not linked to patient enrolment.
- **Marketing and promotion of medicinal products, medical devices and other healthcare technologies:** ANAC identifies key risks in the undue influence of prescribing decisions, sponsorships, consultancy arrangements, financial benefits, and the dissemination of non-transparent scientific information. Key safeguards include adopting **codes of ethics, transparency of transfers of value, tracking meetings between physicians and pharmaceutical representatives and mandatory periodic training**, covering corruption risks associated with promotional activities and the proper management of relationships with pharmaceutical companies.
- **Provision of healthcare services:** ANAC identifies specific risks associated with manipulating accreditation procedures. The main preventive measures include **first- and second-level control plans, inspections, standardised checklists and the rotation of civil servants**. ANAC also pays particular attention to the management of conflicts of interest in accreditation procedures, with a view to monitoring situations in which the public authority has links with the body to be accredited that could compromise its impartiality. Among the preventive measures identified, it recommends (a) the **rotation of inspection team members and prior declarations** by assessors (auditors), **certifying the absence of conflicts of interest**, (b) **spot checks** on these declarations and on the effective application of the rotation principle. **During the payment phase**, in order to prevent the reimbursement of services that are not codified or have not actually been provided, ANAC calls on the health authorities to carry out **strict monthly monitoring of the services provided under the contractual agreement**.
- **Public procurement:** ANAC focuses on **conflicts of interest** throughout the procurement cycle, including **shareholdings in companies** involved in tenders, calling for an assessment of any interference between private and public interests. On patient referrals to private facilities where the healthcare professional also works, ANAC calls for verifying clinical appropriateness, prohibiting undue influence on patients, and ensuring full traceability of activities.

4. Promotional Materials and Artificial Intelligence: The New AIFA Guidelines

On 24 July 2026, the Italian Medicine Agency ("AIFA") published the guidelines on the use of artificial intelligence ("AI") systems in promotional materials ("PM") intended for healthcare professionals (the "**Guidelines**"), which may be updated over time. The Guidelines apply both to PMs prepared with the support of generative AI models (drafting, reviewing or updating of content) and to PMs incorporating interactive AI systems, such as chatbots or virtual assistants designed to provide information on medicines to healthcare professionals.

AI-generated product information remains subject to the standard AIFA submission obligations under Legislative Decree 219/2006. In addition, the Guidelines require that **AI-generated content derive only from certified sources**, which must be attached to the submission with the relevant passages highlighted; chatbot outputs **must link to the exact source**; and companies must describe **the PM and the AI models used**, granting AIFA the credentials needed to carry out checks.

Since generative AI may produce inaccurate citations or outdated data, companies must verify

the accuracy of AI-generated content against the summary of product characteristics, regulatory documentation and validated literature, and document such checks, consistently with the data quality principle under Article 10 of the AI Act. AI remains a support tool only: **the marketing authorization holder and the head of the scientific department remain responsible for the accuracy and compliance of PMs**. Under Articles 4 and 14 of the AI Act, **companies must adopt a "human-in-the-loop" model with adequately AI-literate staff**, and under Articles 9 and 15 **must integrate AI use into their quality management system**, including risk monitoring and periodic stress tests.

Recipients interacting with AI systems must be informed accordingly, and AI-generated content must be labelled and accompanied by a disclaimer on its limitations, recommending recourse *to official sources*. Companies must also submit a scientific-department statement on algorithm validation and supporting technical documentation demonstrating compliance with the AI Act and Regulation (EU) 2016/679, including information on personal data processing.

5. Biotech Act: JURI Backs SPC Extension and Broader Manufacturing Waiver

On 7 September 2026, the European Parliament's Committee on Legal Affairs ("JURI") adopted its opinion on the proposed European *Biotech Act*, supporting a compromise solution that would maintain the possibility of an **additional twelve-month extension of Supplementary Protection Certificates ("SPCs")** for certain biotechnology-derived medicinal products, while at the same time strengthening the **SPC manufacturing waiver** applicable to biosimilar medicines.

Under the compromise supported by JURI, eligible biotechnology-derived medicinal products would continue to benefit from a **potential additional twelve months of SPC protection**, subject to specific requirements relating to **clinical research and manufacturing activities carried out within the European Union**. At the same time, JURI proposed **extending the manufacturing waiver to biosimilar medicines**, allowing manufacturers, under specified conditions, to build up stocks without the current six-month limit before the expiry of the relevant SPC so that they can enter the EU market immediately after protection expires.

Traditionally, SPCs have served to compensate pharmaceutical companies for part of the effective patent term lost as a result of the time required to obtain marketing authorisation. The proposed extension reflects a broader use of SPC-related incentives as an **instrument of European industrial policy**, aimed not only at addressing regulatory delays but also at encouraging companies to locate research, clinical development and manufacturing activities within the European Union and at strengthening Europe's competitiveness in the biotechnology sector.

The *Biotech Act* remains subject to the EU legislative process and its final provisions may therefore differ significantly from the current proposal. However, the latest JURI opinion confirms that the future scope of SPC protection - and the balance between extended exclusivity for innovative medicines and earlier preparation for biosimilar market entry - is becoming an important element of the wider European debate on biotechnology competitiveness.

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