Capsulas

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A quick "flash" on seven key topics to keep top of mind as we kick off the new season and Q4 2026

Background

September has its own back-to-work rituals: catching up on emails, trying to remember a password or two, and discovering that your to-do list has survived the summer perfectly well. Holidays have a curious way of making what happened just before seem much further away than it really is.

But whilst we were swapping meetings for holidays, regulatory, legal and industry developments continued apace. Some topics made the headlines for a few days; others went somewhat more unnoticed; and several deserve a second look now that the new academic year is beginning.

We've selected a few topics. Today we're revisiting them in a quick round-up, and over the next few days we'll be dedicating a Capsulas piece to each one. Because September is also a good time to catch up.

I'm a pharmaceutical company, am I an interest group?

At the end of August, Royal Decree-Law 21/2026 came into force, regulating the activities of interest groups (lobbies) and establishing a new mandatory register for them. The question for pharmaceutical companies is obvious: does this apply to me? The answer may be less obvious. Because, based on the definition in the Royal Decree-Law, we may be engaging in more 'lobbying' - or, in the terms of the regulation, 'influence-purchasing activities'- than we realise. Meetings with officials from the Ministry of Health or contacts with the AEMPS regarding regulatory matters may fall under this definition.

And the consequences are significant. Those carrying out influence-related activities must, amongst other things, register with the Register before engaging in certain contacts with public officials or employees. Furthermore, it is not necessary to meet directly with the authorities: funding trade associations, think tanks or other organisations with the aim of influencing public or regulatory debate is also considered a form of indirect influence.

The new law also introduces new transparency obligations and provides for certain information relating to these activities to be made public. However, the legislation must be validated by the Spanish Parliament before 26 September. In the meantime, perhaps this is a good time to ask ourselves a question: are we carrying out 'activities of influence' without having identified them as such?

Guidelines on exclusionary conduct

The European Commission has just published these Guidelines on the application of Article 102 TFEU, which prohibits abuses of a dominant position, to exclusionary conduct. The fact that the Commission has devoted a document of this magnitude to such conduct is because it is the area in which Article 102 TFEU is most frequently applied.

In the pharmaceutical sector, the application of Article 102 TFEU to exclusionary conduct always raises specific questions arising from the particular characteristics of the pharmaceutical market. The definition of the relevant market is undoubtedly the first issue to consider. Alongside this issue, there are others of great importance on which the Guidelines offer interpretative guidance. This is the case, for example, with predatory pricing, margin

squeezing, discounts or similar practices that may prevent other competitors from entering the market; exclusive supply agreements; or joint offers ('bundling' and 'tying'). Refusal to supply, or the misuse of regulatory or legal procedures, are also areas of risk to be considered, on which the Guidelines offer interesting insights.

It is also worth noting that the Guidelines provide insights into how conduct that might otherwise be considered abusive may be justified if it is objectively necessary or if it generates certain efficiencies without eliminating effective competition.

Notified price at pharmacies

On 31 July, a Framework Agreement was signed between SEVeM (Spanish Medicines Verification System) and the General Pharmaceutical Council of Spain (CGCOF), regulating the implementation and operation of the reimbursement system for the application of the notified pricing regime (the price regime that will apply to units that are not reimbursed) provided for in Article 94(7) of Royal Decree-Law 1/2015.

This agreement, long awaited by the industry, enables the dual pricing system (reimbursed price and notified price) to be implemented in practice for retail products, something which, until now, and, except for a few isolated cases, was only possible for hospital products.

The mechanism will be administered through the PRENO System, managed by the CGCOF. Pharmaceutical companies will continue to supply medicinal products to pharmacies and distributors at the reimbursed price (or at the reimbursed price minus any commercial discounts they deem appropriate, as they have done to date). When a pharmacy dispenses a medicinal product outside the National Health Service (NHS) and charges the patient the (higher) notified price, it must return the difference to the pharmaceutical companies and distributors, as appropriate. The CGCOF, via the PRENO System, will be responsible for calculating these amounts monthly and organising the logistics of the payments.

The system is expected to come into operation from 1 October 2026, with the first companies having already certified their information systems.

Proposal for a European Regulation on public procurement

The end of summer brings with it a far-reaching reform of public procurement: on 9 September, the European Commission presented its proposal for a Regulation on public contracts and concessions, which will replace the three 2014 directives with a single, directly applicable regulation.

Key new features include greater flexibility of selection and financial standing criteria; the strengthening of quality criteria over price, limiting the weighting of the latter; and the restriction of self-cleaning measures to cases where tenderers are subject to grounds for exclusion.

Furthermore, one of the most notable new developments is the introduction of 'European preference' criteria. In certain procurement procedures, measures may be introduced to favour tenderers, goods or services that meet certain requirements relating to their connection with Europe, for example, based on the percentage of production or components of European origin.

However, there is an important caveat: 'European' does not necessarily mean 'from the EU'. These rules may also extend to companies and products from countries with which the European Union has concluded certain international agreements. In practice, this could considerably dilute the effect of the so-called 'European preference' and broaden the range of operators who can benefit from it. The proposal is now going through the legislative

process in the European Parliament and the Council. We will be following its progress closely.

The price is confidential (and the law says so)

For years, the confidentiality of the price and reimbursement conditions of medicinal products has been a subject of debate. This summer, the legislator took an important step towards resolving this issue: Article 97(3) of the Law on Medicinal Products has been amended to expressly recognise the confidential nature of the price and reimbursement agreements, as well as all information derived from them or from their application.And the reform goes further: confidentiality is expressly extended to the contract award prices for public procurement contracts for the supply of medicinal products. Furthermore, the obligation works both ways: it applies equally to the public administration and to the companies that are party to the agreements. The aim is clear: to protect financial terms whose confidentiality is essential to preserving the Spanish NHS's negotiating power and to prevent their disclosure from having an impact on other markets.

The legislator has settled the debate. The ball is now quite literally in the courts' court -and in that of the Council for Transparency and Good Governance. And it would be difficult to understand how the date of a request for access or an administrative decision could be used to circumvent a reform whose very purpose has been to clarify existing doubts regarding the confidentiality of this information. The message from the legislator is now much clearer: the price and reimbursing conditions of medicinal products are confidential.

What will the future Royal Decree on pricing and reimbursement look like?

The long-awaited draft Royal Decree that will regulate the pricing and reimbursement procedure of medicinal products within the Spanish NHS has finally been released for public consultation. And this is no minor update: the text aims to bring a regulatory framework, which had been lagging current practice for years, up to date and to become one of the central pillars of the new landscape for access to, pricing and reimbursement of medicinal products in Spain.

For the first time, the draft sets out detailed regulations governing reimbursement agreements (spending caps, maximum costs per patient, price-volume agreements or outcomes-based schemes), and paves the way for conditional and accelerated reimbursement mechanisms. It also addresses issues of particular sensitivity for companies, such as the confidentiality of reimbursement terms, prices, and the systems governing the price of medicinal products following the loss of exclusivity -such as the reference pricing system or homogeneous groupings.

The draft royal decree still has a long way to go, and it remains to be seen whether it will ultimately be approved and on what terms. In any case, it will be worth following its progress closely: updating legislation that has been out of step with the reality of access to and reimbursing for medicinal products for years would undoubtedly be welcome news. It now remains to be seen whether the final text will live up to the expectations of such a long-awaited reform.

Transposition of the new Product Liability Directive

The deadline for Member States to transpose Directive (EU) 2024/2853 on liability for damage caused by defective products is 9 December 2026.

This new Directive replaces the old 1985 Directive and introduces significant changes which we have already discussed in our Capsulas No. 260, highlighting the aspects we consider most important for companies operating in the pharmaceutical and life sciences sector.