Capsulas

Summary of the presentations given by the Faus Moliner team at the 20th Pharmaceutical Law Course organised by the CEFI Foundation

Lluís Alcover, Joan Carles Bailach, Anna Gerbolés and Claudia Gonzalo participated as speakers. Jordi Faus delivered the closing lecture

The relevance of the HTA Regulation

In his presentation, Lluís Alcover highlighted the significance of the new European Health Technology Assessment Regulation. The Regulation will mark a turning point in the way medicinal products are evaluated in Europe. He explained that this regulation seeks to harmonise clinical criteria among Member States, but at the same time introduces a more complex and demanding framework for pharmaceutical companies. Companies will have to adapt their regulatory and market access strategies from the very early stages of clinical development.

Lluís warned that access to Joint Scientific Consultations (JSCs) will be limited, which could pose a risk of breaching the principle of equality recognised in the EU Charter of Fundamental Rights. There will not be room for everyone, and only some companies will be able to obtain early advice to align their trials with the expectations of the assessment agencies. This limitation raises questions about procedural fairness and transparency in the allocation of opportunities for dialogue with the authorities.

Another critical point highlighted was the possibility that joint clinical assessments (JCAs) may include off-label comparators. This approach will require special attention from companies to ensure that the evidence generated is relevant and robust in relation to the selected comparators. Furthermore, there is some concern about comparing technologies with different regulatory and cost profiles, as this could introduce bias into the assessment and pose a problem when interpreting the assessment results.

Finally, Lluís stressed that the role of developers in defining PICOs (patient population, interventions, comparators and health outcomes) and reviewing draft JCAs will be very limited, which may strain the right to be heard and make it difficult for developers to defend the value of their technology. All of this, he warned, opens a new front of legal and procedural challenges that will require companies to strengthen their regulatory planning and their legal response capacity.

Financing of medicinal products

Joan Carles Bailach spoke about the main challenges that the Draft Law on Medicinal Products and Medical Devices (Draft Law) should address to achieve a more agile system for the incorporation of therapeutic innovation and, at the same time, a more predictable one for the companies operating within it. To this end, the Draft Law should incorporate or better define the following instruments.

Firstly, Joan Carles explained that the new Law should include early dialogue as an instrument enabling companies and the Administration to formally initiate price and reimbursement negotiations once the CHMP has issued a positive opinion on the marketing authorization. This tool would substantially reduce the timeframes for financing and would place Spain at the forefront in Europe, as many countries have yet to incorporate it into their legislation.

Secondly, the new Law should include instruments aimed at reducing access times and making the process more predictable. These include the accelerated financing procedure and conditional financing.

The accelerated financing procedure would shorten the processing times for certain medicinal products of public health interest, such as orphan medicinal products, advanced therapies, oncology or antimicrobial medicinal products, among others. In this regard, the Secretary of State for Health, during his appearance before the Health Committee of the Spanish Parliament on 28 October 2025, announced that the new Law will incorporate a period of less than 90 days, especially for medicinal products intended to cover unmet medical needs.

Conditional financing would allow for the provisional reimbursement of medicinal products subject to clinical or economic uncertainty, conditional on the generation of new real-world evidence. This model would facilitate faster access to innovative therapies, while maintaining risk control for the National Health System through review clauses, clawback mechanisms or provisional discounts.

Both instruments would contribute to more equitable access, reduce current legal uncertainty and balance the need for speed with that of sustainability and rigor in decision-making.

Finally, Joan Carles considered that the new Law should contemplate the possibility of conventional termination in certain price and reimbursement procedures, allowing the Administration and companies to modify or terminate the agreement when circumstances beyond the control of the parties arise. This measure would provide greater legal certainty and flexibility, promoting more efficient management of uncertainty and an effective collaborative relationship between industry and the Administration.

New developments in advertising

In the session dedicated to advertising, Anna Gerbolés addressed the new developments introduced by the new regulatory framework on the promotion of medicinal products. In particular, she examined those included in the Draft Law on Medicinal Products. She also reviewed the Draft Royal Decree on the promotion of medical devices, analysing the possible impact that this draft might have on the future regulation of medicinal product promotion.

Among the most relevant new developments regarding advertising in the Draft Law, Anna referred to those introduced in the sanctioning framework. One of them is the reclassification of the infringement of the rules on promotion of medicinal products, which will no longer be considered “very serious” but “serious”, thus aligning the sanction with that established for the irregular promotion of medical devices.

Another significant development is the introduction of a new infringement concerning the prohibition of promoting medicinal products prior to their marketing, aimed at closing the debate opened following the Supreme Court ruling of March 2025. This ruling determined that promotion prior to the price and reimbursement resolution does not infringe Royal Decree 1416/1994, regulating the advertising of medicinal products for human use, if it includes information about the price of the product. During the session, it was noted that this new infringement could be contrary to Directive 2001/83/EC, as it would establish an absolute prohibition not foreseen in that Directive. The case law of the Court of Justice of the European Union -in particular, judgments C-374/05 (Gintec, 2007) and C-786/18 (Ratiopharm, 2020) has reiterated that absolute restrictions cannot be imposed in a field of full harmonization. It is therefore likely that this infringement will be removed from the final text.

Lastly, Anna analyzed the measures included in the Draft Royal Decree on the promotion of medical devices, warning of the risk that some of them might be unduly transferred to the field of medicinal products, despite their different regulatory frameworks. For example, the broadening of the concept of "promotion" for medical devices -which would include any meeting financed by the company to present the characteristics of a product- contrasts with the narrower view that applies to medicinal products.

Similarly, the absolute prohibition of offering hospitality at promotional meetings, as foreseen for medical devices, would not be compatible with the Directive if applied to medicinal products, since Article 94 allows hospitality if it is moderate and subordinate to the scientific or professional purpose of the meeting. An absolute prohibition on hospitality would also be contrary to the European framework.

Artificial intelligence in the medicinal product life cycle

During her presentation, Claudia Gonzalo addressed how artificial intelligence (AI) is not only advancing in the healthcare field but is also beginning to be integrated throughout the entire life cycle of a medicinal product: from discovery and clinical trial design to manufacturing and pharmacovigilance. Her presentation revolved around a key idea: AI does not replace human responsibility, but it does redefine the way critical decisions are made in the pharmaceutical sector.

She explained that AI is already accelerating phases such as the discovery of new molecules or the selection of patients for clinical trials, and that regulatory agencies now recognize evidence generated by algorithmic systems. She also pointed out that the European Union's Good Manufacturing Practices are preparing to incorporate a new Annex 22 dedicated to AI, and that in the commercialization phase this technology is already being used to improve the detection of adverse effects and optimize supply management.

However, she warned that this progress will only be sustainable if it is governed under two principles: the risk-based approach -according to which regulatory requirements should increase in proportion to the criticality of the decision- and the quality and traceability of data, all within the context of building the highest possible level of trust in the system.

Finally, she highlighted the strategic role of the legal department in the integration of AI. Successful implementation cases, she noted, share common elements: a clear inventory of models and risks, the adaptation of contractual clauses to algorithmic environments, and internal procedures that guarantee the quality of both system and the data that feeds it. Her closing message was clear: it is not about slowing down innovation but about accompanying it monitoring structures that ensure its development with safety and traceability.

Closing Conference

Jordi Faus began his speech by highlighting the high level of participation in the course, and his satisfaction at seeing how the work carried out by those who have participated in submitting proposals to the Spanish Administration concerning the regulations being developed has not been in vain. As Ana Bosch (Farmaindustria) pointed out, the proposals have been listened to attentively and, in many cases, incorporated into those that the Ministry of Health is willing to present and defend. This speaks highly of the Administration but also of those who have formulated the proposals, especially Farmaindustria, CEFI, and some companies and professionals who have participated in the process.

As for the current situation, in which "everything related to the regulatory core is under review" (César Hernández), Jordi stressed that it is essential

to recognize the role of the industry and of lawyers specializing in pharmaceutical law, pointing out that "what is going to be approved are legal rules, so I encourage you to participate in everything you can (…) with a broad perspective, considering relevant economic, social, and ethical aspects, and putting yourselves in the position of the managers, as Manuel Cervera also said, because what is needed is a calm debate built on solid foundations and with few, if any, prejudice".

In this context, Jordi agreed with the idea expressed by Javier Padilla: in times of uncertainty such as the present, it is advisable to avoid overreacting and to maintain the commitment to more Europe. Remaining firmly committed to the core values of the EU is of the utmost importance. Having public health systems whose main objective is to protect the health of citizens and help them overcome disease is a social achievement that must be nurtured every day. It is, ultimately, a question of culture. The same applies to understanding -as pointed out in the Commission's July Communication ("Strategy for European Life Sciences to position Europe as the world's most attractive place for life sciences by 2030"), that beyond preserving competitiveness, we must approach these matters considering that "this is also a strategic investment in intergenerational fairness, as the aim is for Europe to lead with purpose, so that innovation serves people and the planet, both now, and for generations to come".

On the other hand, Jordi once again insisted that committing to Europe must also mean guaranteeing the full effectiveness of European Union law, citing case law that requires national provisions contrary to EU law to be set aside. Supporting this view, he noted that administrations, for example, should not prevent a product from being placed on the market (even on the private market) nor prohibit its promotion once the European Commission has granted a marketing authorization.

Regarding the 2024-2028 Pharmaceutical Strategy, Jordi pointed out that it is a government action plan approved by a resolution of the Council of Ministers of 10 December 2024 -a text that may be used in any interpretation of any regulation or action by the General State Administration.

The plan's objectives are divided into chapters: (i) equitable access to medicinal products and sustainability of the NHS; (ii) promotion of research, development and innovation; and (iii) autonomy, which encompasses both the idea of ensuring the competitiveness of the sector and its contribution to strategic autonomy through a solid, resilient and eco-sustainable supply chain.

In relation to these objectives, the importance of conceiving pharmaceutical policy as a genuine national policy was highlighted, which should also integrate industrial, social and employment aspects. Perhaps one of the positive side effects of the pandemic has been precisely to make us aware of the importance of what we now call strategic autonomy, and of the need to support those who concentrate their investments, efforts and daily work in production units. Jordi considered it noteworthy that the strategy recognizes, as current challenges for the sector, (a) the greater complexity of research and development of therapies to meet unmet needs and (b) the vulnerability of supply chains caused by an exodus of production facilities because of globalization and cost pressures.

Regarding the sustainability of the system, Jordi provided a historical perspective on this issue, highlighting that the challenge of sustainability has always been present, but pointing out that the measures to address it should be adapted to the current reality. We are not, Jordi said, in the 1980s, "when the task was to adopt measures to exercise a certain control over a significant portion of public funds, the use of which depended on the decision of the prescribing professional." In the 21st century,

the products with the greatest budgetary impact are ones where the industry's ability to influence the volume of demand is low or even non-existent. For this reason, if the crux of the matter in terms of sustainability lies in in the tension between the developers' ability to supply technologies and the capacity of public health systems to structure their demand appropriately as part of their public policies, the priority should be to work on how demand is structured, not on creating obstacles for supply, especially when discussing about therapeutic areas where the industry's ability to influence the volume of demand is very low or even non-existent.

Finally, it was pointed out that access issues are closely related to the individual rights of patients, highlighting that, although in Spain the right to health protection is not a fundamental right but only a guiding principle of administrative activity, certain case law recognizes that the fundamental right to life and physical integrity must mean more than the mere right to exist.

After reviewing the actions outlined in the Strategy, Jordi concluded by expressing his hope that the new rules, like the medicinal products they regulate, will be of high quality, offer legal certainty, and establish an effective framework to support a favorable environment for innovation, for the benefit of society as a whole and especially of patients.

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