Capsulas

Updates on advertising of medicinal products in the new EU Pharmaceutical Legislation

We are launching a series of CAPSULAS focused on the new EU Pharma Package to explain its main implications by topic in a clear and practical way

Introduction

Commentary on the new pharmaceutical legislation has focused on a number of highly relevant aspects, such as the incentives system, market access, shortages, and environmental impact. By contrast, developments relating to the advertising and information of medicinal products, despite their direct impact on companies' day-to-day activities, have received comparatively less attention.

The new Directive will introduce significant changes in this area. Some of these developments reflect criteria already outlined in EU case law and regulatory practice; others, however, entail substantive new adjustments. In any event, their implementation will require a review of internal policies and promotional materials and activities.

As this is a Directive, its application will require transposition by the Member States. However, the margin of discretion is not unlimited. In its judgment of 8 November 2007, Gintec, C-374/05, the Court of Justice of the European Union (CJEU) held that Directive 2001/83/EC brought about complete harmonisation in the field of advertising of medicinal products. Accordingly, unless expressly authorised by that Directive, Member States are not permitted to adopt additional restrictions. For this reason, it is particularly relevant that the new Directive includes, in certain areas, explicit provisions allowing Member States to adopt more restrictive approaches. Outside these cases, additional absolute limitations may not be imposed, unless justified on public health grounds.

Against this background, the main developments introduced by the new Directive in relation to advertising of medicinal products are outlined below.

1. The concept of advertising expands to include campaigns not mentioning a specific product

One of the most significant developments is the express incorporation of the CJEU's doctrine on the scope of "advertising of medicinal products", as established in its judgment of 22 December 2022, Euroaptieka, C-530/20. According to this doctrine, any communication aimed at promoting the purchase of medicinal products qualifies as advertising, even if it does not refer to a specific product.

This interpretation is expressly reflected in the new Directive (recital 137 and Article 175.1(h)), which expressly includes, among the situations covered by the concept of advertising, that relating to medicinal products without reference to a specific product.

In practice, this significantly broadens the concept of advertising. With this broader scope, generic promotional campaigns relating to a "range" or category of products may fall within the concept of advertising if they encourage their purchase, even where no specific medicinal product is identified.

The transposition of this concept into national legal systems raises certain questions, as it does not

seem reasonable to subject this type of advertising to the same regime as the one applicable to the promotion of specific medicinal products. For example, in Spain, it would not make sense to require the inclusion of the minimum content that must appear in all communications addressed to healthcare professionals, as set out in Articles 10 and 14 of Royal Decree 1416/1994.

Accordingly, it may be expected that national transposition will introduce specific conditions for this type of messaging. On the other hand, the new Directive provides for the possibility for Member States to directly prohibit the advertising that does not refer to a specific medicinal product (Article 177).

This provision likely stems from the CJEU's judgment of 27 February 2025, DocMorris, C-517/23, regarding the distinction between the advertising of medicinal products and the advertising of distribution channels (e.g. pharmacies or distribution platforms), which are subject to different legal regimes, with only the former falling within the scope of Directive 2001/83/EC.

Advertising of medicinal products (including that falling within the concept outlined by the CJEU in the Euroaptieka case) is a matter of complete harmonisation. Therefore, unlike the promotion of pharmacies, Member States may not impose absolute prohibitions unless expressly authorised by the directive (as is now envisaged) or unless such restrictions are justified on public health grounds, as we had the opportunity to discuss during the Life Sciences Practice Group (LSPG) session held in Barcelona in April 2025, where Dr. Morton Douglas, from the German firm Friedrich Graf von Westphalen, shared his views on this interesting judgment.

Finally, as an indication of the EU legislator's intention to limit excessive consumption of medicinal products, and alongside the aforementioned empowerment of Member States, the new Directive expressly introduces a prohibition on promotional activities that encourage excessive or inappropriate use of medicinal products (Article 176.3(ba)), a requirement not expressly set out in the current framework.

2. Objective advertising and tighter restrictions on comparative advertising

The new text reinforces an existing trend towards more "neutral" advertising of medicinal products.

The new Directive expressly requires advertising to disseminate objective and impartial information (recital 136). This results in two explicit prohibitions in comparative advertising: (i) highlighting negative aspects of another medicinal product; and (ii) suggesting that the advertised medicinal product is safer or more effective than another, unless such comparison is objectively supported by the SmPCs (Article 176.4).

This represents a substantial shift.

Furthermore, the idea that comparisons relating to safety, quality or efficacy are permitted only where supported by the SmPCs, raises an important practical question: must the comparative conclusion be expressly stated in the SmPC, or is it sufficient that the underlying supporting data are referenced in it? The text does not provide clarity on this point. Nevertheless, it is clear that comparisons based solely on external studies, not reflected in the SmPC will not be permitted.

Regarding biosimilars, new Article 176.4 of the Directive must be interpreted in light of recital 136, which, although it is not expressly incorporated into the operative provisions, states that claiming that a biosimilar is not interchangeable with the

original biological medicinal product or another biosimilar derived from the same originator constitutes misleading advertising.

3. Advertising to healthcare professionals extends to nursing staff

Recitals 140 and 141 acknowledge that certain medicinal products - particularly innovative, complex, or combinati on therapies - require not only prescribers and dispensers, but also those administering them, to understand their characteristi cs. On this basis, the new Directive extends the scope of adverti sing to include professionals authorised to administer medicinal products (Article 175).

However, Member States retain discretion to apply stricter rules for adverti sing directed at such professionals (Article 177.8).

In Spain, adverti sing of prescription-only medicinal products to nursing staff is already permitted in certain circumstances. This suggests that transpositi on of the Directi ve will largely follow a conti nuity-based approach. The existing framework is therefore likely to be maintained, allowing adverti sing in relati on to medicinal products for which nursing staff have prescribing authority or a defi ned role under protocols and guidelines issued by the health authorities.

4. End of the "minimal value" exception: general prohibiti on of incentives

With regard to the regime governing incentives, current Arti cle 86 of Directi ve 2001/83/EC includes, within the concept of adverti sing, "the gift, offer or promise of any benefi t or bonus", while excluding them where their intrinsic value is minimal. This excepti on is likewise refl ected in Spain in Article 17 of Royal Decree 1416/1994.

The new Directive removes this exception (Article 175). Consistently, Article 183 establishes that no incentives may be provided in the context of advertising to healthcare professionals. This is a significant change, as it eliminates the legal basis that has allowed low-value materials or courtesy items, as provided for in Article 10 of the Code of Practice of Farmaindustria (EPFIA's national member).

It should be emphasised that the new rule does not amount to a prohibition of hospitality. This point is particularly relevant because, in Spain, certain authorities have historically adopted a restrictive interpretation of the prohibition on incentives, considering that such prohibition effectively entailed a ban on hospitality in promotional settings. This interpretation was reinforced by the fact that Royal Decree 1416/1994 regulates hospitality only in the context of scientific or professional events.

However, this interpretation is not consistent with either the current Directive or the new one, which expressly provides that the prohibition on incentives does not prevent the provision of hospitality at promotional events, provided that it is strictly limited to the primary purpose of the event and is not extended beyond healthcare professionals (Article 183(2)).

5. Samples: possible extension to dispensers

While the new text does not substantially revise the regime governing samples, it introduces an important clarification. Recital 135 indicates that samples may be provided not only to prescribers but also to those who dispense medicinal products.

Accordingly, Member States may, on an exceptional basis, allow the provision of samples

of non-prescription medicinal products (OTC) to dispensers (Article 185(2)).

This development is significant in the Spanish context, where the authorities have traditionally adopted a more restrictive interpretation, considering that the rules prohibit the provision of samples to pharmacists, even though this is not expressly provided for in Royal Decree 1416/1994.

The new Directive appears to align with CJEU case law and with the debate that emerged following the judgment of 11 June 2020, Ratiopharm / Novartis Consumer Health, C-786/18, which confirmed that the Directive permits the provision of samples of non-prescription medicinal products.

Nevertheless, the new provisions still leave certain grey areas, particularly as it would have been desirable to clarify whether the regime applicable to the provision of samples of prescription medicinal products and that applicable to OTC samples are equivalent, given that the above-mentioned case law had already recognised that they are distinct regimes.

6. Transparency of transfers of value: moving beyond self-regulation

In connection with this matter, the he new rules, depart from the idea that even minimal incentives may influence prescribing decisions (recital 139.a).

The new Directive introduces new obligations for Member States and marketing authorisation holders regarding transparency of transfers of value (Article 186.4a). Where no national rules exist, Member States must provide a public webportal with links to the transparency disclosure platforms operated by industry associations or the marketing authorization holders, who will be required to provide such links and ensure the accuracy and timely publication of the information.

While a fully harmonised EU transparency regime is not yet imposed, the shift is significant: transparency moves from a purely self-regulatory framework to integration within public information systems.

7. Other developments: shortages, public advertising, and new content restrictions

First, Member States may suspend the advertising, targeted at both healthcare professionals and the public, in situations of shortages or risk thereof (Article 177.7). While justified from a public health perspective, the concept of “risk of shortage” remains broad and may create legal uncertainty if not further specified through objective criteria. The text itself provides that the suspension shall be withdrawn as soon as the shortage or risk of shortage ceases.

Second, Member States may restrict the use of the trademark or designation of the medicinal product in reminder advertising directed at the general public, limiting it instead to its active substance (Article 178.2).

In addition, new content restrictions are introduced for advertising directed at the general public. In particular, the existing prohibition on endorsements by scientists and healthcare professionals is extended to include endorsements by healthcare institutions or facilities (Article 179). This may have a significant practical impact, for example in relation to the use of imagery, settings, or references evoking pharmacies, hospitals, or other healthcare environments.

Finally, the new Directive expressly prohibits referring, in advertising, to the fact that a medicinal product has been granted a marketing authorisation.