Global Compliance in Transition: Navigating the Evolving Regulatory Landscape for Healthcare Communications


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Introduction: New Era of Healthcare Communications Amid Global Regulatory Change and Rising Demands for Evidence-Based Engagement

The landscape for advertising, promoting and scientifically communicating about medicinal products and medical devices is undergoing rapid and profound transformation. This shift is driven by a convergence of tightening global regulations, evolving expectations from healthcare professionals (HCPs) and patients, and a growing demand for robust, evidence-based information. As of 2026, the industry is facing what has been described as a "compliance cliff", with new regulatory frameworks governing the vertical sectors for medicinal products and medical technologies, and stricter data privacy standards fundamentally reshaping the external communication environment. In this context, the sharing of knowledge, information and collaboration with external stakeholders has never been more critical, serving as a powerful catalyst for innovation in science and medical research by translating ideas into practical advances.

Legitimate scientific communications, when tailored to their audience and context, are intended to convey accurate and relevant information that supports healthcare needs, builds trust and stimulates debate on complex or contentious issues. These communications are essential for fostering knowledge exchange and innovation, yet the boundaries between scientific exchange and promotion are increasingly scrutinised by regulators – particularly when the subject matter involves unapproved or investigational uses. Global regulatory authorities have significantly intensified their scrutiny of advertising claims, requiring all promotional materials to align strictly with approved indications and the terms of the marketing authorisations. The introduction of publicly accessible portals has increased transparency and accountability, making it easier for regulators and competitors to identify and challenge non-compliant activities. Simultaneously, data privacy regulations impose strict controls on the use of patient data, limiting the scope for behavioural targeting and personalised advertising.

Competition law considerations are increasingly significant, especially regarding comparative advertising claims. As companies seek to differentiate their products in crowded markets, comparative advertising – where one product is compared to another – has become more common. However, such claims are subject to close scrutiny under both European Union (EU) and national competition laws, which require that comparisons be objective, verifiable and not misleading, while avoiding unfair disparagement of competitors or market confusion. Misleading or inadequately substantiated comparative claims can draw regulatory scrutiny, result in civil litigation or damage reputation. It is therefore essential that comparative statements are supported by robust evidence and presented in a fair and balanced manner, with clear disclosure of any limitations or differences in study design, patient populations or outcomes. These challenges are compounded by market fragmentation, longer buying cycles and pricing pressures, all of which make it more difficult to identify and reach relevant patient populations. As therapeutics become increasingly specialised and competition intensifies, compliant and credible communication is more important than ever for effective product differentiation.

The risk associated with off-label promotion has also heightened, with a notable increase in legal actions against companies promoting unapproved uses. This has made marketers more cautious and, in some cases, has stifled the communication of innovative uses that have not yet received regulatory approval. The industry is consequently expected to ensure that all external communications are not only accurate and evidence-based but also strictly within the boundaries of approved indications.

Patterns of interaction among HCPs and patients are also shifting dramatically. HCPs are experiencing information overload and increasing time constraints, leading to a decline in traditional face-to-face interactions and a preference for concise, clinically relevant and efficient exchanges. At the same time, patients are becoming more empowered and digitally literate, seeking personalised information through online platforms and social media. This evolution renders generic, "one-size-fits-all" campaigns less effective and underscores the need for tailored, transparent and scientifically validated communications. Trust in the healthcare industry has eroded, with both professionals and patients demanding authenticity and independent, peer-reviewed information rather than overtly promotional content. Brands must therefore focus on providing balanced, factual and transparent information to build and maintain credibility.

The research and development of innovative medical products has become increasingly challenging as political, economic, regulatory and scientific forces converge to demand greater cost efficiency, clinical relevance and patient centricity. Success in product development now depends on the ability to draw upon clinical insights, source and communicate relevant data, and deploy resources to support the gathering of evidence required for informed assessment of safety, efficacy and therapeutic value, enabling timely clinical adoption. Outreach efforts to disseminate clinical research findings can drive changes in health policy and clinical practice and ultimately improve health outcomes. In a healthcare environment that is ever more patient-centric and cost-sensitive, national health systems, HCPs, patients and advocates are all calling for up-to-date information to support more equitable, inclusive and evidence-based decision-making.

The concept of unmet medical need, embedded in regulatory systems worldwide, incentivises the development of new therapeutic approaches by identifying and addressing gaps in current treatment options, particularly for vulnerable populations.

When standard treatment options are exhausted, discussions between physicians and patients about non-standard, often investigational, options become necessary. These conversations are guided by scientific data and clinical assessment of the patient's unique circumstances, informing decisions about expanded access to unapproved treatments. The evolution of clinical decision support systems, largely based on digital tools, is designed to ensure that accurate information reaches the right person, in the right format, through the right channel, at the right time, thereby optimising healthcare delivery, outcomes and resource allocation. In response to this dynamic environment, the industry is increasingly required to develop deeper insights into treatment pathways and decision-making processes, creating strategic roadmaps to optimise product value and market access.

Technological advances have greatly expanded the range of media available for promotional and scientific communication with healthcare providers, patients and other stakeholders. The dissemination of medical practice and scientific information via social media is on the rise, as the scientific community seeks to foster connectivity, overcome barriers to access, stimulate debate and gather perspectives from both professionals and laypersons. However, this expansion also brings the risk of misinformation, which can promote practices lacking scientific evidence and undermine scientific integrity. Companies must therefore implement robust governance and monitoring systems to ensure that all digital communications are compliant, scientifically sound, and – where comparative claims are made – fully substantiated and fair.

Regulatory expectations continue to evolve in response to these challenges. Across key jurisdictions, the fundamental requirement is that information provided to the marketplace is accurate, reliable and does not mislead or cause harm to treatment decision-making. This necessitates that all communications – whether promotional or scientific – are underpinned by robust evidence, accurately characterised and appropriately disclaimed, with risks and benefits clearly presented. While these core principles underpin regulatory approaches globally, there are variations in how different jurisdictions seek to achieve these aims. For example, in the United States, changes in administration have led to shifts in regulatory engagement and enforcement, injecting a degree of uncertainty for stakeholders.

The external environment for the promotion, advertising and scientific communication of medicinal products and medical devices is more challenging and complex than ever before. There is a greater need for engagement with both patients and HCPs, and success now depends on the ability to deliver transparent, scientifically validated information through personalised, omnichannel engagement – ensuring compliance, building trust and supporting informed healthcare decisions.

This chapter examines recent regulatory developments in scientific and medical communications, including those relating to unapproved uses that have traditionally been considered non-promotional. It explores how regulators are increasingly scrutinising such communications for their potential promotional impact. In addition, the chapter addresses significant recent developments across key geographical regions – including the United States, the EU and the Asia-Pacific region, with particular attention to China, Japan and Korea – concerning the regulation of advertising and promotion, with particular focus on requirements for the disclosure of product risks, the substantiation of claims and the limitations of promotional communications.

Dissemination of Non-Promotional, Scientific Communications

In January 2025, the United States Food and Drug Administration (FDA) finalised a non-binding guidance document concerning firms' communications regarding scientific information on unapproved uses (SIUU) of approved or cleared medical products (SIUU Guidance). The SIUU Guidance focuses on communications that are non-promotional in nature, providing recommendations for the dissemination and discussion of off-label reprints, clinical practice guidelines and reference texts, among other sources. Its scope is limited to communications directed at HCPs who are involved in making clinical practice decisions for the care of individual patients. Consequently, communications to HCPs acting in a payor or researcher capacity, as well as communications to non-HCP audiences such as patients or caregivers, fall outside its remit. In the SIUU Guidance, the FDA clarifies that it does not intend to use a firm's dissemination of these types of non-promotional, scientific communications "standing alone" as evidence of a new intended use. However, this "standing alone" language indicates that the FDA may consider such communications alongside other evidence (e.g., express or implied promotional statements; circumstances surrounding product distribution) as part of an inquiry into whether a company is promoting its product for a new or unapproved intended use.

The SIUU Guidance, which finalises a previous draft version published in 2023, adheres to the FDA's longstanding position that firms may disseminate certain forms of truthful, non-misleading, factual, unbiased scientific information relating to unapproved uses of medical products. The guidance expands on the 2023 draft, which had marked a significant departure from the FDA's earlier stance on the dissemination of off-label scientific information in several respects. Notably, the draft guidance had expressly acknowledged that firms could develop their own presentations about off-label reprints to share with HCPs. In response to industry and stakeholder comments, the FDA takes this further in the final SIUU Guidance, clarifying that a firm-generated presentation may be based on any type of source publication described in the guidance (i.e., clinical practice guidelines, scientific or medical reference texts, and digital clinical practice resources) in addition to off-label reprints. The SIUU Guidance, however, delineates what constitutes appropriate communication in a firm-generated presentation. Specifically, it identifies two "communication techniques" as inappropriate for SIUU communications: (i) presentations that "encourage the unapproved use of the medical product based on elements other than the communication's scientific content", such as celebrity endorsements, emotional appeals unrelated to scientific content, gifts, promotional tag lines, jingles, and premium offers; and (ii) presentations that include any "calls to value that pre-judge the benefit(s) of the medical product for patients", defined as a "communication technique that includes both a call to action and a value proposition that tells the audience what this action will translate into for them" (e.g., stating "Click here to access the full article for free" is acceptable, but "Click here to start improving your patients' lives today" is not). Additionally, the SIUU Guidance recognises that social media and in-person visits with HCPs can both be appropriate in certain circumstances for disseminating SIUU of approved or cleared medical products.

The SIUU Guidance also recommends that SIUU communications only describe studies that are "scientifically sound". While the FDA provides some general concepts to inform the definition of these terms, it does not offer clear definitions,

and the guidance appears to reserve significant discretion for the FDA to assess whether the standard is met on a case-by-case basis. For example, the SIUU Guidance states that studies other than randomised, double-blind, concurrently controlled superiority trials "may...be scientifically sound when adequately designed and conducted", that "a scientifically sound study could include an early-phase randomised, double-blind, parallel assignment clinical study with a prespecified statistical analysis plan comparing the pharmacokinetics, pharmacodynamics, safety, and immunogenicity of two... products", and that "other examples of studies that could be consistent with this recommendation include meta-analyses, cohort or case-control studies, open-label studies, single-arm studies, externally controlled trials, and non-interventional (observational) studies". Furthermore, the SIUU Guidance does not address how this new standard should be understood in relation to existing substantiation standards in other contexts, such as the "scientifically appropriate and statistically sound" standard the FDA has established for promotional communications consistent with FDA-required labelling (CFL communications). This proliferation of varying standards for scientific communications may prove challenging for firms to distinguish and manage.

Finally, the SIUU Guidance provides numerous recommendations regarding the presentation of communications materials and disclosures that should accompany SIUU communications. Although the SIUU Guidance attempts to provide detailed recommendations, the extensive disclosure expectations it enumerates may be onerous in practice. For example, the guidance recommends including both a copy of the FDA-approved labelling and separate statements reiterating certain points from the labelling, as well as a list of standard disclaimer-type statements providing extensive contextual information. Perhaps most burdensome is the SIUU Guidance's recommendation that SIUU communications also include a description of any conclusions from other relevant studies that "evaluated the same or similar hypothesis or research questions" that are "in conflict with the conclusions from the studies or analyses described", a phrase that is not further clarified or defined.

EU pharmaceutical law expressly requires that advertising and promotional materials for medicinal products must be compatible with the approved particulars of the Summary of Product Characteristics (SmPC), which sets out the agreed conditions of use for each authorised product. Consistent with the Council of Ministers' position during the legislative process, and as confirmed by European jurisprudence, the concept of "advertising of medicinal products" is interpreted broadly, with a focus on the promotional purpose of the communication. Advertising and promotion of unapproved medicinal products or unapproved therapeutic uses are expressly prohibited. The European courts distinguish between promotional and non-promotional communications – including those conveyed through digital and electronic means – by considering whether the communication is likely to promote the prescription, supply, sale or consumption of medicinal products. Purely informative material, without promotional intent, falls outside the scope of EU advertising rules. This distinction is also reflected in the European Federation of Pharmaceutical Industries and Associations Code of Practice, which clarifies that the code does not seek to regulate non-promotional medical, scientific or factual information, nor activities directed at the general public relating solely to non-prescription products.

For medical devices, EU law prohibits the use of text, names, trademarks, images or other signs that could mislead users or patients about the intended purpose, safety or performance characteristics of the device. This includes prohibiting claims that ascribe unsubstantiated functions or properties, create false impressions regarding treatment or diagnosis, or suggest uses outside the device's approved intended purpose.

In recent years, the EU regulatory environment has shifted towards greater transparency, particularly regarding clinical trial data. The heads of national agencies and the European Medicines Agency (EMA) have emphasised the need for effective communication strategies that present accurate, meaningful and actionable information to diverse audiences – including patients, the public and HCPs – to build trust in scientific advances and regulatory systems. Since 2010, the EMA has adopted policies to facilitate both proactive and reactive disclosure of clinical trial data, aiming to allow developers, researchers and third parties to learn from past experience, verify analyses and conduct further research in the interest of public health.

Directive 2001/83/EC remains the cornerstone of EU law on the advertising and control of medicinal products, establishing that advertising must be accurate, balanced and not misleading, and must not encourage irrational or excessive use. The Court of Justice of the European Union (CJEU) has played a central role in interpreting these principles. The CJEU has ruled that "advertising of medicinal products" encompasses not only the promotion of specific medicines but also more general promotions, such as discounts or bundled sales. National bans on advertising based on price or special sales are compatible with EU law if they serve public health objectives and prevent irrational use. The CJEU has further clarified that advertising which promotes the prescription, supply, sale or consumption of medicinal products – even if not specified – falls within the Directive's scope, while advertising that merely influences the choice of pharmacy does not. Restrictions on advertising must be proportionate and justified by public health needs; for example, a blanket ban on pharmacy advertising was found to breach EU free movement rules.

The CJEU has also held that information from third parties, such as journalists, can constitute advertising if it is intended to promote a medicine. The distinction between information and promotion is particularly relevant for online content: genuinely informational material may fall outside the advertising prohibition, but promotional content is subject to the Directive.

National courts apply these principles within their own legal frameworks, sometimes imposing additional requirements. For example, German courts have set strict limits on the value of promotional gifts and have held companies liable for advertising by paid influencers. Spanish courts have clarified the rules for promotion during the period between marketing authorisation and pricing resolution. National authorities and courts also interpret and enforce advertising rules for medical devices, as the EU Medical Devices Regulation leaves advertising largely to national law.

Self-regulatory bodies enforce codes of practice that supplement statutory requirements. The UK's Prescription Medicines Code of Practice Authority or PMCPA has ruled on cases involving the promotion of prescription-only medicines to the public, misleading or exaggerated claims, and the boundaries between promotional and non-promotional activities. Sanctions can include corrective statements and public reprimands.

The general principles established by EU law and jurisprudence are that advertising of medicinal products must be objective and not misleading, and must not encourage inappropriate use. Restrictions must be justified by public health concerns and proportionate to their aims. Both statutory

and self-regulatory frameworks work in tandem to ensure high standards of public health protection and fair competition, with ongoing reforms – such as the EU Pharma Package – aiming to clarify and update the legal landscape in light of recent case law and evolving regulatory expectations.

Asia, by comparison, has largely prohibited or limited off-label promotions, though the regulatory landscape across major jurisdictions – particularly China, Japan and Korea – is undergoing notable evolution as authorities seek to balance strict promotional controls with growing recognition of the need for legitimate scientific exchange. While the overarching prohibitions remain in place, recent regulatory developments in each of these jurisdictions reflect increasing sophistication in distinguishing between impermissible off-label promotion and permissible dissemination of scientific and medical information – a distinction that, as discussed above, has been at the centre of regulatory guidance in the United States and the EU.

In China, the regulatory framework governing pharmaceutical promotion and scientific exchange has continued to tighten, even as authorities refine the permissible boundaries of "academic promotion" (学术推广). China's Drug Administration Law and the Measures for the Administration of Drug Advertisements, enforced by the State Administration for Market Regulation (SAMR) and the National Medical Products Administration, strictly prohibit the advertisement or promotion of drugs for unapproved indications. Unlike the US approach under the SIUU Guidance, China has not established a formal safe harbour for the dissemination of off-label scientific information by pharmaceutical companies. However, in practice, the regulatory environment has increasingly recognised a distinction between commercial promotional activity and academic exchange conducted through registered medical representatives. Under China's Medical Representative Registration and Filing System, which has been progressively implemented since 2020, medical representatives are permitted to engage in academic promotion activities – such as conveying drug information to HCPs, collecting clinical usage data and providing drug safety information – but are expressly prohibited from engaging in direct product sales or promotional activities that extend beyond approved indications. In 2025, SAMR continued to pursue enforcement actions against companies engaged in off-label advertising, with particular focus on digital marketing channels and social media platforms that have become increasingly prominent in the Chinese healthcare communications landscape. Notably, China's approach to scientific exchange remains considerably more restrictive than the US framework, and companies operating in China should exercise particular caution when structuring medical affairs communications to ensure they do not cross the line into promotional activity as defined under Chinese law.

Japan has similarly maintained a strict prohibition on off-label promotion but has developed a more structured regulatory framework for the provision of scientific information to HCPs. The Ministry of Health, Labour and Welfare (MHLW) Guidelines for the Provision of Sales Information on Prescription Drugs (Sales Information Guidelines), originally issued in 2018 and subsequently refined, establish a comprehensive framework governing how pharmaceutical companies may communicate with HCPs about prescription drugs. Under the Sales Information Guidelines, information provided to HCPs must be based on valid scientific evidence and presented in an accurate and balanced manner, and must not be misleading. Companies are required to establish internal review and oversight committees to ensure compliance with these standards. Importantly, the Sales Information Guidelines distinguish between "sales information provision activities" – which are subject to these regulatory requirements – and purely academic or scientific activities, such as publishing in peer-reviewed journals or presenting at academic conferences, which fall outside their scope. In 2025, Japan's approach to off-label scientific exchange continued to evolve, with MHLW and the Pharmaceuticals and Medical Devices Agency providing further clarifications regarding the permissible scope of information provision in response to unsolicited requests from HCPs. While Japanese law does not provide a formal analogue to the US SIUU Guidance permitting proactive dissemination of off-label scientific information, the practical operation of the Sales Information Guidelines permits a degree of responsive communication about unapproved uses where initiated by an HCP and supported by sound scientific evidence. Companies operating in Japan must, however, maintain careful documentation of the circumstances surrounding such communications and ensure that internal compliance structures satisfy the monitoring and audit requirements established by the Sales Information Guidelines.

In Korea, the Ministry of Food and Drug Safety (MFDS) and the Korea Fair Trade Commission jointly oversee pharmaceutical advertising and promotional practices under the Pharmaceutical Affairs Act and the Fair Labelling and Advertising Act. Korean law prohibits the advertising of prescription drugs to the general public and imposes strict requirements on promotional communications directed to HCPs, including a prohibition on advertising unapproved indications or uses. The Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) Code of Practice supplements these statutory requirements, establishing additional standards for ethical interactions with HCPs and the substantiation of promotional claims. In 2025, MFDS intensified its scrutiny of digital and online pharmaceutical marketing, issuing updated guidance on the regulation of pharmaceutical advertising through social media, messaging platforms and other digital channels – a development that parallels similar regulatory trends in the United States and the EU. Korea's approach to the boundary between promotional activity and scientific exchange has also been the subject of increased regulatory attention. While Korean authorities have not issued guidance comparable to the US SIUU Guidance permitting the proactive dissemination of off-label scientific information, the KPBMA Code of Practice permits the sharing of scientific data in certain non-promotional contexts, such as at medical conferences and in response to unsolicited requests from HCPs, provided that such communications are accurate, balanced and consistent with sound scientific evidence. As in China and Japan, the practical distinction between permissible scientific exchange and impermissible off-label promotion remains an area of considerable regulatory risk, requiring companies to invest in robust local compliance frameworks.

Taken together, the regulatory developments across China, Japan and Korea underscore a broader trend in the Asia-Pacific region towards more structured – but still restrictive – frameworks for pharmaceutical communications. While none of these jurisdictions has adopted the degree of regulatory accommodation for off-label scientific exchange seen in the US SIUU Guidance, each has moved towards greater clarity regarding the boundaries between permissible scientific communication and prohibited promotional activity. For multinational companies, the key challenge lies in reconciling these varying standards with the more permissive frameworks in the United States and, to a degree, the EU, requiring carefully calibrated global compliance strategies that account for meaningful differences in both substantive requirements and enforcement approaches.

Direct-to-Consumer (DTC) Advertisements

Unlike many other jurisdictions, the United States currently allows manufacturers of prescription drug products to market directly to consumers. The FDA regulates DTC advertising under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. The 1962 Kefauver-Harris Amendments require prescription drug advertisements to include a "true statement" summarising side effects, contraindications and effectiveness. In 1969, the FDA modified its regulations so that broadcast ads (television and radio) need only present the "major statement" of risks and contraindications, provided they also make "adequate provision" for disseminating the approved labelling.

The FDCA further requires that DTC television and radio ads state the drug's name, conditions of use, and present the major statement clearly, conspicuously and neutrally. In November 2023, the FDA finalised the "CCN Rule", establishing five standards for presenting the major statement: use consumer-friendly language; ensure audio is as understandable as the rest of the ad; present the major statement in both audio and text for sufficient duration; use easy-to-read text; and avoid distracting elements during the major statement. These standards aim to address longstanding concerns that DTC ads inadequately convey risk information.

While the CCN Rule clarifies requirements, some standards remain broad and subjective. In December 2023, the FDA issued guidance to help interpret these standards, but ambiguity persists, particularly regarding terms like "consumer-friendly" and "readily understandable". The rule applies to television and radio ads, but the FDA has not clarified its scope regarding newer platforms such as streaming services, podcasts and social media.

The current administration, including United States Department of Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr., has criticised DTC advertising, citing concerns about unnecessary medication use, rising healthcare costs and conflicts of interest. On 9 September 2025, President Trump directed the FDA and HHS to strengthen oversight of DTC advertising, emphasising transparency and accuracy. The FDA responded with a press release announcing a crackdown on deceptive drug advertising and plans to remove the "adequate provision" framework, which it described as a loophole undermining informed patient consent.

On the same day, the FDA sent letters to all drug and biologic sponsors, and approximately 100 additional letters targeting specific ads alleged to be deceptive. The agency has since issued regular warning and "untitled" letters, focusing on television commercials and other media, including online videos, sponsored links, patient websites, podcasts and print materials. Common issues cited include overstated efficacy claims, misleading comparative claims, broadening approved indications, inadequate risk disclosure and use of attention-grabbing visuals during risk statements. The FDA has also criticised ads for failing to comply with dual modality requirements (audio and text) and omitting important risk information.

Although the FDA has not proposed new rules to amend current regulations on adequate provision in broadcast ads, its increased enforcement activity signals a more aggressive stance on DTC advertising. Whether this trend will continue under the current administration remains uncertain.

The proposed legislative revisions to EU pharmaceutical law were positively adopted by the European Parliament and the European Council in 2026 and will replace the existing regulatory framework following the transition period. The legislative proposal continues to restrict advertising of prescription medicinal products as well as medicinal products containing substances classified as psychotropic or narcotic to the general public. In addition, the proposed legislation imposes additional restrictions on advertising to the general public by requiring the advertising not to contain, among others, any material that: gives the impression that a medical consultation or surgical operation is unnecessary, by offering a diagnosis or by suggesting treatment by mail; refers to a purported recommendation by scientists, HCPs, or persons who are celebrities with the effect of encouraging the consumption of medicinal products; suggests the safety or efficacy of a medicinal product because it is "natural"; or refers to claims of recovery in improper, alarming or misleading terms.

Claims Substantiation

Though enforcement by the Office of Prescription Drug Promotion (OPDP) had briefly waned in the early 2020s, a significant uptick in OPDP enforcement activity since mid-2023 has provided some insight into the FDA's enforcement priorities. OPDP's enforcement letters in recent years have focused on key issues raised by the FDA's guidance on CFL communications, which addresses communications regarding information and data that do not appear within a product's approved labelling, but are nonetheless consistent with such labelling. OPDP's recent enforcement letters indicate that key areas of FDA focus include the scientific appropriateness and statistical soundness of benefit claims, the sufficiency of context surrounding benefit claims and the presentation of risk information in promotional materials.

Based on the number of warning and "untitled" letters issued, one of OPDP's most common concerns relates to the sufficiency of evidence supporting benefit claims. Beginning with an "untitled" letter issued to Mirati Therapeutics in August 2024 related to clinical data provided on an HCP-branded website related to KRAZATI, the FDA has consistently issued warning and "untitled" letters related to the presentation of certain efficacy-related data (e.g., time-to-event endpoints) from single-arm oncology trials. In its letters, the FDA broadly asserts that these promotional materials are false or misleading, alleging that the companies misleadingly presented observed effects as attributable to their products when the study design was not capable of supporting such representations. Even in cases where the information included in cited materials was limited to relatively straightforward data presentations devoid of conclusory statements of safety and efficacy or a promotional tone, the FDA has taken the position that such materials are making "claims", "conclusions" or "representations or suggestions" because, among other things, even mere presentation of the data "conveys to the audience... that the data are relevant to their understanding of...efficacy". Given the FDA's recent focus on efficacy claims that do not appear in product labelling, manufacturers engaging in such communications should be particularly conscious to avoid claims or characterisations regarding CFL data where there are material study design or statistical limitations, as in the case of *post hoc* analyses, failed material endpoints and analyses not controlled for multiplicity. Additionally, manufacturers should take care when drafting disclaimers, ensuring that they are robust, prominent and complete as it relates to disclosing limitations, and clear where conclusions cannot appropriately be drawn. However, the FDA's recent "untitled" letters indicate that even adhering to these limitations may be insufficient to avoid regulatory enforcement in certain contexts where the FDA may view the underlying data as categorically insufficient or misleading perhaps including, for

example, as it relates to drugs approved under the accelerated approval pathway. It will be important to continue closely scrutinising product efficacy claims to ensure, *inter alia*, that the underlying data is sufficiently robust to support the claim, that appropriate context and disclaimers are conveyed and cover any material limitations, and that the presentation is appropriate for the intended audience.

The general principles established by EU law and jurisprudence are that advertising of medicinal products must be objective and not misleading, and must not encourage inappropriate or excessive use. Any restrictions on advertising must be justified by public health concerns and be proportionate to their aims. Both statutory and self-regulatory frameworks operate in parallel to ensure high standards of public health protection and fair competition, with ongoing reforms – such as the EU Pharma Package – aiming to clarify and update the legal landscape in response to recent case law.

While advertising and promotion in the EU are governed by a harmonised regulatory framework, enforcement is carried out at the national level by regulatory authorities or self-regulatory bodies. In accordance with the prevailing EU legislative framework, national enforcement regimes must be proportionate, dissuasive and effective. Enforcement actions are subject to judicial review by national courts, which may refer questions of interpretation to the CJEU for a preliminary ruling where issues are novel and of general importance for the uniform application of EU law. The case law of the CJEU is highly instructive in guiding how harmonised advertising and promotional rules should be interpreted and applied. The CJEU has consistently held that advertising of medicinal products can harm public health by encouraging improper, ill-conceived or irrational use, and that advertising material itself may contribute to such risks.

In addition to these legal and regulatory principles, the EMA has recently clarified its position on the use of real-world evidence (RWE) in support of therapeutic claims. The EMA recognises that RWE – data derived from sources such as electronic health records, patient registries and observational studies – can play a valuable role in supplementing clinical trial data, particularly in the post-authorisation phase or where randomised controlled trials are not feasible. However, any therapeutic claims made in advertising or promotional material must be robustly substantiated. RWE may be considered part of the overall evidence base, but it must meet high standards of scientific validity and reliability, external validity and cannot be used to support claims that go beyond the approved SmPC. The EMA has issued guidance on the appropriate use of RWE, emphasising that such data must be transparent, reproducible and subject to rigorous methodological standards to ensure that any therapeutic claims are accurate and not misleading. In summary, the EU regulatory and jurisprudential framework requires that advertising of medicinal products is strictly controlled to protect public health, with enforcement mechanisms at both national and EU levels. The use of RWE is increasingly recognised by the EMA as a valuable tool in establishing therapeutic claims, provided it is used within the boundaries of regulatory approval and meets stringent evidentiary standards.

Conclusion

This chapter has explored the increasingly complex global regulatory environment for engaging and communicating with HCPs and patients. Across all major jurisdictions, advertising, promotion and scientific exchange are being reshaped by stricter regulations, greater transparency requirements and growing demand for robust, evidence-based information. Authorities in the EU, US and Asia – including China, Japan and Korea – are intensifying scrutiny of both promotional and non-promotional communications, with a focus on claim substantiation, RWE and clear separation between scientific information and covert promotion.

A central challenge is navigating a patchwork of statutory, regulatory and self-regulatory frameworks. While common principles such as objectivity, accuracy and the prohibition of misleading promotion underpin global regulation, enforcement remains fragmented. National authorities and courts interpret these principles differently, and self-regulatory bodies add further oversight. Multinational companies must therefore adopt flexible, locally informed compliance strategies.

The rise of digital platforms and social media has expanded the reach of communications but also increased the risk of misinformation and regulatory breaches. As HCPs and patients become more digitally engaged, the demand for tailored, transparent and scientifically validated information grows. Declining trust in the healthcare sector highlights the need for authenticity, independent evidence and clear communication of both benefits and risks.

Another trend is the emphasis on patient centricity and stakeholder collaboration. Patients are increasingly involved in healthcare decisions, and their perspectives are sought in research, development and regulation. Authorities and industry bodies are responding with greater transparency, including expanded disclosure of clinical trial data and clearer guidance on RWE. Agencies such as the EMA and FDA have issued guidance to ensure scientific communications are accurate, balanced and properly contextualised.

Looking ahead, ongoing regulatory evolution – such as the EU Pharma Package, new FDA rules on DTC advertising and reforms in the Asia-Pacific region – will require companies to remain vigilant and proactive. Success will depend on integrating legal, regulatory and ethical considerations into all external engagement, fostering transparency and accountability, and building trust with HCPs and patients.

Key issues for ongoing discussion include operationalising global compliance amid local variation, the role of digital governance in managing emerging risks and the evolving boundary between scientific exchange and promotion. Continued dialogue among industry, regulators, HCPs and patients will be essential to ensure external communications both comply with legal requirements and support improved public health outcomes.

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