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Legal Guides

Practical cross-border insights into pharmaceutical advertising

Pharmaceutical Advertising 2022

19th Edition

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Global Trends in Regulatory Compliance Challenges in Advertising and Promotion


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Introduction

Globally, pharmaceutical and healthcare product companies have increased their spending year on year on the advertising and promotion of their products. Country-by-country spending on advertising and promotion is principally driven by both the local regulatory environment and the potential revenue generation in the applicable market. For example, healthcare expenditure in the United States ("U.S.") is the highest in the world where direct-to-consumer ("DTC") advertising for prescription-only medicines is permissible. In 2020, U.S. healthcare spending grew nearly 9.7%, reaching $4.1 trillion or $12,530 per person, which accounted for nearly 20% of the Gross Domestic Product. Not surprisingly, there is correspondingly high spending on a wide array of promotional activities, including television and digital advertising, social media advertising, and disease awareness campaigns.

In general, global companies are having to adapt their advertising techniques to match the technological advancements in the industry and evolving healthcare practices. With healthcare globally focusing on early disease prevention, bespoke patient-centric treatment pathways and diagnosis, as well as increased accessibility for all, the timing and target audiences of advertisements are being shifted and becoming ever more important.

These developments also raise novel regulatory compliance and enforcement questions in relation to the oversight of the advertising and promotional rules, which are enacted to regulate business conduct and external engagement activities.

As a general matter, regional and national law and the industry codes of practice define "advertising and promotion" broadly. "Advertising and promotion" is couched in terms of the business conduct undertaken by companies and the effect of such conduct to promote the prescription, recommendation, supply, administration or consumption of healthcare products. For example, the established case-law of the European Courts clearly distinguishes between promotional and non-promotional activities. The genesis of the advertising and promotional rules created in EU pharmaceutical law is to avoid undue influence through specific promotional incentives that could bring about the risk of encouraging the irrational use of a medicinal product. The regulatory oversight/control is to prevent any excessive and ill-considered advertising that could affect public health.

Likewise, in the U.S., the Food & Drug Administration ("FDA") regulates the advertising and labelling, including promotional labelling, of drugs and medical devices. This encompasses virtually any manufacturer communication with a promotional purpose and may include, for example, product brochures, websites, social media posts, sales representative detailing visits, and journal and television advertisements. The FDA does not regulate non-promotional, so-called "scientific exchange", though the contours of this safe harbour are not clearly defined.

China's Advertising Law also defines advertising activities broadly, covering any channels or media where a product distributor or service provider directly or indirectly markets or introduces the products or services it distributes or provides. The term promotion is not clearly defined under Chinese law; however, the Code of Practice on the Promotion of Pharmaceutical Products, issued by the Pharmaceutical Association in China ("RDPAC Code"), defines promotion as any activity undertaken, organised or sponsored by a member company, which is directed at healthcare professionals ("HCPs") to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical products through all methods of communications, including the internet. Member pharmaceutical companies in China voluntarily agree to comply with the RDPAC Code, as generally accepted baseline practices for drug promotion in China.

Common risk areas relating to control of advertising and compliance with promotional rules are well known to the life sciences industry, but in order to respond to evolving healthcare practices and technological advances, there is a need to reconsider the traditional regulatory compliance risks to determine whether internal policies and processes continue to be adequate and relevant to addressing novel uncharted situations, for example, as the result of the rise of digital health and changes to healthcare practices. The rapid pace of innovation in the sector brings with it significant legal, regulatory and policy challenges. In the key global regions, there is an apparent lack of singular legislation to cover digital health, resulting in a patchwork of different regimes being applied, which do not address adequately the distinct features of such health technologies.

Against this background, this chapter therefore seeks to highlight those emerging cross-border compliance issues in light of the ever-changing external environment in which companies operate. Such sector-specific rules governing healthcare products also interface with the anti-bribery and corruption rules in connection with the offering, promising or giving of an advantage, and requesting, agreeing to receive or accepting an advantage, as exemplified by the Memorandum of Understanding signed between the UK Prescription Medicines Code of Practice Authority and the Serious Fraud Office.

Patient Engagement

Patients contribute to health innovations and policy-making. The World Health Organization ("WHO") recognises that patient engagement is an integral part of healthcare and a critical component of ensuring that health services are clinically relevant and safe. The process empowers individuals to make informed decisions about their care and treatment options. In addition, it enables policy-makers to allocate the resources that are aligned with patients' priorities to achieve the sustainability and responsiveness of health systems worldwide.

In the same vein, many global regulatory authorities and health technology agencies, respectively responsible for product approval and market access, also acknowledge the importance of patient engagement in: (a) gaining greater insights into disease burden and its management; and (b) generating patient-specific evidence to inform an assessment of benefit/risk and therapeutic value of a new method of treatment. In determining market access, policy-makers consider that effective patient engagement helps in identifying unmet needs and the development and subsequent authorisation of effective treatments to ensure that they are based on robust input from patients reflecting their preferences, values and priorities.

For example, last year, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") initiated a public consultation on their Proposed Patient and Public Involvement Strategy for 2020–2025 with the aim of eliciting feedback in order to adopt a more systematic approach to listening to and meaningfully involving patients and the public.[1] This partly stemmed from criticism from Baroness Cumberlege in her report of the Independent Medicines and Medical Devices Safety Review, in which she recommended that: "The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work." The Patient and Public Involvement Strategy aims to ensure there is a systematic means of engaging and involving patients and the public in the work of the MHRA. It is suggested that this could be achieved by a number of proposals, including such considerations as incorporating: (a) patient and public views on the benefits and risks of medicinal products in the new Innovative Licensing and Access Pathway; (b) patient and public input in the regular review of patient safety "signals"; and (c) new sections in assessment report templates that act as a prompt to check that patient and public engagement has been considered.

Similarly, the European Medicines Agency ("EMA")'s Regulatory Science Strategy to 2025 clearly reinforces the core value of integrating patient relevance as part of the evidence-generation process. Delivering for patients in order to fulfil and prioritise unmet medical needs and to ensure accessibility to innovative treatments to benefit patients is a key pillar of the European Commission's proposed pharmaceutical strategy for Europe, which was published in 2020. The 2020 EMA scientific strategy also emphasises the role of leveraging patients' voices in the regulatory decision-making process. The newly unveiled European Health Initiative – the world's largest Public Private Partnership in the life sciences sector with a €2.4 billion budget – also aims to include the perspective of patients at every stage of its research projects. The initiative's Strategic Research and Innovation Agenda ("SRIA") sets out five key goals, including a commitment to focus on addressing the needs of patients and HCPs who use new health technologies. The SRIA also focuses on developing ways of assessing the value of innovative solutions to patients, carers and others.

Likewise, the U.S. FDA has released a series of guidance documents in recent years as part of its patient focused drug development ("PFDD") programme, as mandated by the 21st Century Cures Act enacted in 2016. The goal of the PFDD programme is to help ensure that patients' experiences, perspectives, needs and priorities are captured and meaningfully incorporated into drug development and evaluation. The FDA has conducted numerous public meetings as part of the PFDD programme over the years in order to elicit patient perspectives on a wide range of disease areas, such as autism, alopecia areata, lung cancer, chronic pain, and sickle cell disease.

There is, however, a tension between the objectives of patient engagement and the regulation of advertising and promotion of healthcare products. In the majority of the countries outside the U.S., DTC advertising for prescription-only medicines is expressly prohibited. For example, in China, prescription drugs can only be advertised in government-designated medical and pharmaceutical journals intended for HCPs. A prescription drug advertisement must state prominently that "this advertisement is meant to be read only by medical and pharmaceutical professionals". And, even in the U.S., where DTC advertising is permitted, manufacturers generally are prohibited from engaging in promotion of drugs and medical devices prior to marketing authorisation. Accordingly, such patient engagement activities must be carefully planned and controlled to avoid them being characterised as disguised promotion of investigational medicines or prescription-only medicines without appropriate medical supervision. The process of properly managing the information exchanges between companies and patients may become critically important, including the need to communicate information that is factual, non-promotional, balanced and fair.

Novel Trial Design

Increasingly, new innovative products are being researched and developed for patients with specifically defined characteristics so that treatment can be individualised. Very often, such studies involve a small population. Simply put, the aim of individualised therapy is to deliver the right drug to the right patient. The administration of the right drug to the right patient could reduce healthcare costs by enhancing drug efficacy and reducing drug toxicity, and thereby resulting in reduced hospital admissions and utilisation of healthcare services. With the advent of targeted therapies, biomarkers provide an increasingly promising means of individualising therapy. Such biomarkers can be prognostic as regards disease outcome or predictive of drug response. Pharmacogenomics is a critical component of individualised medicine and is the study of the role of inheritance in individual variation in drug response. The application of specific pharmacogenomics markers or genome sequencing might enable early identification of common or rare variants associated with drug response or toxicity that are clinically impactful in terms of the magnitude of the treatment-related effects. Such an approach might then allow enrichment of clinical development with responders and/or exclusion of patients at risk of adverse events. The benefits of such an approach would be a smaller sample size, lower costs of performing such a trial, and greater likelihood of a positive result.

The novel trial design may involve potentially eligible patients being referred to specialist centres by HCPs in the primary care setting in order to track down a sufficient number of participants who may fulfil the criteria set out in the checklist for initial screening for possible enrolment into an interventional study. In order to improve efficiency and effectiveness of referral, referring centres and/or referring HCPs are financially incentivised. Arrangements for such financial compensation in the form of a referral fee, if not properly managed and rationalised, could potentially raise serious compliance concerns including inducement. For example, in the U.S., both the American Medical Association ("AMA") and the American College of Physicians ("ACP") have issued guidance stating that physicians should not accept payment solely for referring patients to clinical trials, going so far as to call such a practice "unethical".[2] Rather, these authorities take the position that any payment to physicians should be set at fair market value for their time and effort in performing recruitment activities such as reviewing medical records or discussing the possibility of clinical trial enrolment with patients. Another challenge arises when investigators are paid a "bonus" for meeting certain enrolment targets in a clinical trial. The U.S. Department of Health and Human Services Office of Inspector General has

expressed concern in a report entitled *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research* that payment of such bonuses can erode the informed consent process and lead to enrolment of subjects who are not eligible for the study due to the desire of investigators to earn the bonus.

The need to improve efficiency in enrolling eligible trial participants will become more challenging not only for studies that involve small populations but also in response to policy change imposed by regulatory authorities. For example, the MHRA and the Health Research Authority ("HRA") overseeing clinical studies in human subjects in the United Kingdom, in collaboration with clinical research experts, have developed proposals to replace the clinical trials regulation in the UK with a risk-based framework.[3] This includes a proposal to introduce a sunset clause on approvals of clinical trials – such approval will lapse automatically if no participant has been recruited (in contrast to the current legislation where approval is valid indefinitely), thus putting pressure on sponsors to recruit a sufficient number of patients within a limited timeframe.

In China, clinical trials must be implemented within three years after approval. If no participant has been recruited within three years from the date of approval, the clinical trial approval will automatically become invalid. As a result, sponsors have real pressure to recruit patients in a timely manner. Restrictions on marketing practices involving HCPs can be found from laws and regulations related to anti-bribery and anti-corruption ("ABAC"), while the statutory provisions do not provide specific guidance on common marketing practices. Due to such constraint, it is not a common practice for pharmaceutical companies to directly engage and incentivise HCPs for referring patients. Against this background, numerous online platforms have been launched in China with an aim to address sponsors' patient recruitment needs. These online platforms are usually operated by Clinical Research Organisations and they act as an intermediary between pharmaceutical companies and patients. Since these online platforms will interact with patients and HCPs directly, there can be compliance risks relating to ABAC and data protection.

Balance of Public Health and Legitimate Promotion

COVID-19 infiltrated nearly all aspects of healthcare in the last few years, and advertising is no exception. Claims are made daily in the press, on television, radio and social media by government ministers, scientists and members of the public. Some of these claims are supported by clinical data, but the interpretation of this clinical data can impact what claims are made. Providing clinical data is needed to support claims by scientists, explaining the impact of the virus and the effect of the vaccine. The intention is often to encourage the public to have the COVID-19 vaccine in order to protect public health. In certain situations, such communication is necessary to correct the circulating misinformation. For example, the COVID-19 pandemic prompted the Advertising Standards Authority ("ASA") to implement a fast-track reporting system due to the substantial growth of "misleading, harmful or irresponsible claims around the current COVID-19 situation". Joint action by the ASA and MHRA resulted in three rulings against different companies who claimed their unlicensed IV drips could prevent COVID-19.[4] Two of these advertisements were on company websites, and the other was posted on two separate posts on the company Instagram account.

Similarly, in the U.S., the FDA and the Federal Trade Commission ("FTC") have played an active role throughout the pandemic in monitoring and taking action against companies and individuals making fraudulent, false or otherwise misleading claims about COVID-19. Since 2020, the FTC has sent hundreds of cease-and-desist letters ordering companies to stop making baseless claims that their products and supposed therapies can treat or prevent COVID-19.[5] The FDA and FTC have also issued numerous joint warning letters to companies allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to treat or cure COVID-19.[6]

Vaccine hesitancy for COVID-19 in certain sections of the population has provided the opportunity for alternative treatments to be made available on the market. These treatments are often advertised with medical claims that are not capable of being substantiated. Anthony Grant (trading as Resonator.uk) sold an electronic device used to generate bio-resonance, which was advertised as being capable of destroying COVID-19. Information presented on the company's website and Facebook page stated that the device destroyed the virus by "shaking it to pieces" and could replace COVID-19 vaccines. The device was not CE-marked and provided no supporting evidence. Advertisements of these devices on public forums like Facebook prompted government ministers, scientists and HCPs to respond reactively and educate in language that simplifies the science and potential health issues.

In the U.S., the Department of Justice ("DOJ") has pursued enforcement action against fraudulent COVID-19 treatments and vaccines. For example, DOJ filed a criminal wire fraud and false statements case in July 2021 against a licensed naturopathic doctor who allegedly was offering homeoprophylaxis immunisations and fabricating COVID-19 vaccine cards that stated that the holders, who had received the naturopath's product,[7] had in fact received Moderna's COVID-19 vaccine. The defendant also administered homeoprophylaxis immunisations and claimed that they satisfied California school vaccine requirements and falsified, fabricated and altered records that were submitted to California schools. In April 2022, the defendant in this case pleaded guilty to one count of wire fraud and one count of making false statements related to healthcare matters, and is awaiting sentencing scheduled for July 2022.

Advertising breaches related to COVID-19 were prevalent in the caseload of the Prescription Medicines Code of Practice Authority ("PMCPA"). With almost 50 cases mentioning COVID-19, pharmaceutical companies were subject to numerous allegations of promotion. These included promotion of vaccines prior to authorisation, the sharing of news articles using the word "safe" to describe the respective company's COVID-19 vaccine, and sales representatives contacting National Health Service ("NHS") workers, hospitals and other NHS organisations during the pandemic when told by the PMCPA this was not appropriate due to the pandemic.

COVID-19-related advertising violations are also prevalent in China. In the combat against such violations, it has been made clear in the "Supreme Court, Supreme Protectorate, Ministry of Public Security and Ministry of Justice's Opinions on Punishing the Crimes Hindering the Prevention and Control of COVID-19", released in February 2020, that false advertisements related to the prevention or control of COVID-19 may result in criminal liability in serious cases. Local enforcement authorities have made continuous efforts to penalise companies for falsely advertising products that can purportedly prevent or treat COVID-19 infections. The State Administration for Market Regulation ("SAMR") and its local counterparts have even published several batches of typical cases to foster an awareness of compliance. To name a few, a Hebei-based biotechnology company was fined CNY1 million for falsely advertising its product as "anti-COVID-19" via the WeChat platform in 2020, and a Tianjin pharmacy was fined CNY2 million for misleadingly advertising ordinary drugs as "anti-COVID-19" drugs on a poster in 2020.

Digital Health

Digital health encompasses a broad spectrum of technologies such as the Internet of Things, virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, tools enabling data exchange and storage and tools enabling remote data capture and the exchange of data and sharing of relevant information across the health ecosystem. Such technologies aim at creating a continuum of care and have proven potential to enhance health outcomes by improving medical diagnosis and supporting data-based treatment decisions and personalised self-management of care. These technologies include digital therapeutics, which are essentially patient-facing software applications that assist patients to treat, prevent or manage a disease or condition, such as cognitive behavioural therapy through their mobile devices.

In the U.S., the FDA has grappled with promotional issues related to digital health technologies in both the medical device context as well as the drug context, and this is an area that continues to evolve. In 2018, the FDA published a proposed framework for prescription drug use related software ("PDURS"). PDURS may include, for example, companion applications marketed for use with prescription drugs, such as dose calculators and patient adherence applications. Under the proposed PDURS framework, the FDA would regulate PDURS "output" as promotional labelling that must be submitted to the FDA's Office of Prescription Drug Promotion ("OPDP") and comply with FDA promotional requirements.

The rise of the digital transformation of healthcare can be disruptive. Its implementation may give rise to certain compliance risks, including fraud and abuse and potential risk of off-label promotion, as the underlying technologies could potentially intertwine with the practice of medicine and decision-making on treatment options and patient monitoring.

Social Media

Social networks have become an important health and information resource to facilitate public engagement in health-related issues, with platforms such as Instagram, Facebook, TikTok and LinkedIn amassing billions of users worldwide. There is also a steady rise of pharmaceutical influencers, often HCPs who have a celebrity-level following (for example, "*doctor.mike*", who has 4.4 million followers on Instagram at this point in time), and who the public view as trusted authorities. These influencers produce content ranging from short TikTok videos detailing symptoms of certain diseases, to providing medical opinions on topical issues.

In addition, companies increasingly pay celebrity influencers to advertise their medicines and medical devices on social media and in other media outlets, and these postings have triggered regulatory enforcement against the companies paying them to promote their products. For example, the U.S. FDA issued a warning letter to Duchesnay, Inc. in 2015 based on statements made by reality star Kim Kardashian as part of her paid promotion of the company's morning sickness drug, Diclegis. In 2021, the FDA issued an untitled letter to another company, Biohaven Pharmaceuticals, based on statements made by Kim Kardashian's sister Khloe on a talk show in her role as a paid spokesperson for the company's migraine treatment, Nurtec ODT.

Companies may take advantage of social media platforms to provide information to the public, provided that the content adheres to good practices and applicable regulatory requirements. However, it is easy to fall short of the requirements when there is no control as to how far the audience of the initial posting can reach. One of the most scrutinised platforms (for example, by the PMCPA in the UK) is LinkedIn. Due to the variety of connections individuals have on the platform (ranging from qualified professionals to members of the public), simply liking posts has been deemed promotional by the PMCPA. The PMCPA has stated that the liking of posts and press releases about unlicensed medicines by UK employees of a pharmaceutical company could potentially alert one's connections to the activity and therefore be considered proactive dissemination of material.[8] Even including the name of an unlicensed product and its indication in a job role description was found to have breached the national code.[9] Sharing an article has also been considered as offending the advertising rules in a case where an employee of a pharmaceutical company shared an article on LinkedIn on the prescribing behaviour of cardiologists and how to price new medicines in relation to a prescription-only medicine.[10] The PMCPA considered that on the balance of probabilities not all of the employee's connections would have been HCPs and therefore the sharing of this article with the employee's network was considered promotion of a prescription-only medicine to the public. Retweets on Twitter have the same effect as sharing LinkedIn posts, even more so, as the platform is not historically known to be a professional networking site.

The U.S. FDA has also played an active role in regulating promotion on social media, issuing warning and untitled letters in connection with a variety of platforms, including Facebook, Twitter and Instagram. Additionally, the FDA issued three draft guidance documents focused on promotion on social media in 2014, which, while not yet finalised, play an important role in guiding companies' practices on social media. Underlying the FDA's approach to social media in each of the draft guidance documents is the principle that promotion on social media is subject to all of the same requirements as promotion through any other medium, including the need to convey information in a truthful and non-misleading way with appropriate balance and safety information. Applying traditional promotional rules to social media platforms can be difficult, however, and may raise a variety of issues, including when a company may be responsible for user-generated content and how information may be appropriately conveyed on character-limited platforms like Twitter.

Pursuant to China's Advertising Law, all advertisements published through mass media must be explicitly marked "advertisement" and must not be disguised as news coverage. All advertisements that promote products or services, directly or indirectly, via internet media such as websites, webpages and internet applications in the form of texts, pictures, audios, videos or other forms are subject to the jurisdiction of the Interim Measures for the Administration of Internet Advertising. Online advertising of medicinal products is deemed DTC advertising through public media. Consequently, prescription drugs cannot be advertised online. Similar to other types of advertisements, online advertisements for over the counter ("OTC") drugs and medical devices must also be approved by local counterparts of the National Medical Products Administration ("NMPA") before being released online. In the past few years, enforcement authorities in China have been launching enforcement campaigns targeting deceptive and illegal internet advertisements. Pharmaceutical advertisements were included as a high-priority target, and the most common issues with pharmaceutical advertising are unscientific or misleading advertisements disguised as introduction to knowledge on health and wellness, illegal reference to authorities such as healthcare professionals, scientific experts and patients, and posting pharmaceutical advertisements without obtaining advance approval. The internet and social media, which has great social influence and wide coverage, specifically search engines, e-commerce platforms, mobile applications and social media accounts, have been the focuses of such enforcement campaigns.

Conclusion

The life sciences and healthcare sector is currently being buffeted by the great waves of change in the external environment that will have a significant bearing on how companies conduct their research and development and commercialisation activities to the success of their business. In this highly regulated sector, compliance should accordingly evolve and adapt to ensure that good practices continue to be applied in external engagement with the relevant stakeholders involved in the research and development, as well as healthcare delivery, to optimise patient care and public health protection.

Acknowledgments

The authors would like to thank Sarah Blankstein and Alice Du for their invaluable assistance in the writing of this chapter. Sarah is an associate based in the Washington, D.C. office. She provides legal and strategic advice to pharmaceutical and medical device companies on a wide array of FDA regulatory matters, with a focus on regulatory risk management, promotional compliance matters, good manufacturing practices, and product development. Sarah also regularly provides regulatory counsel for transactions as well as complex internal investigations and government enforcement matters involving promotional, product quality and safety reporting issues. Alice is based in the Shanghai office. She advises pharmaceutical, biotechnology, medical device and healthcare companies on a wide range of regulatory and compliance matters, including cross-border collaboration, market access and commercialisation strategies, and post-market compliance.

Endnotes

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