COUNTRY COMPARATIVE GUIDES 2023

The Legal 500 Country Comparative Guides

United States

PHARMACEUTICAL ADVERTISING

Contributor

King & Spalding LLP

Nikki Reeves

Partner | nreeves@kslaw.com

Seth H. Lundy

Partner | slundy@kslaw.com

Heather Bañuelos

Counsel | hbaneulos@kslaw.com

Gillian Russell

Counsel | grussell@kslaw.com

This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in United States.

For a full list of jurisdictional Q&As visit **legal500.com/guides**

UNITED STATES
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In the United States, pharmaceutical advertising is regulated under federal and state laws. The primary federal laws are the Food, Drug, and Cosmetic Act (FDCA) and the Federal Trade Commission Act (FTCA). The FDCA grants the U.S. Food & Drug Administration (FDA) broad authority over the advertising and marketing of prescription drugs. The FTCA prohibits "unfair or deceptive acts or practices in or affecting commerce," including the dissemination of false advertising for drugs. Through mutual agreements, FDA maintains primary jurisdiction over the labeling of all drugs and the advertising of prescription drugs, while FTC holds primary authority over the advertising of non-prescription, over-the-counter (OTC) drugs. State consumer protection laws also prohibit false or misleading advertising.

Pharmaceutical promotion and advertising also may implicate other federal laws, including the Anti-Kickback Statute (AKS), Civil Money Penalties Statute (CMPS), the civil False Claims Act (FCA), and similar state laws.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Voluntary guidelines issued by trade associations and medical professional associations may apply to pharmaceutical advertising and marketing. In addition, the National Advertising Division (NAD), a non-judicial, industry self-regulatory body, adjudicates advertising disputes brought by consumers competitors or on its own initiative.

a) Codes applicable to companies and healthcare professionals (HCPs) include the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code); PhRMA's Direct to Consumer Advertising Principles; PhRMA's Principles on Responsible Sharing of Truthful and Non-Misleading Information; the Accreditation Council for Continuing Medical Education Guidelines; and the American Medical Association Guidelines. These guidelines address a range of activities, including industry funding for continuing medical education, engaging HCPs as speakers or consultants, and providing gifts or items of value to HCPs.

b) These self-regulatory codes and professional guidelines are voluntary and hold no legal authority alone. However, some states have made the PhRMA Code mandatory for pharmaceutical companies operating within their borders.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Codes applicable to companies and healthcare professionals (HCPs) include the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code); PhRMA's Direct to Consumer Advertising Principles; PhRMA's Principles on Responsible Sharing of Truthful and Non-Misleading Information; the Accreditation Council for Continuing Medical Education Guidelines; and the American Medical Association Guidelines. These guidelines address a range of activities, including industry funding for continuing

medical education, engaging HCPs as speakers or consultants, and providing gifts or items of value to HCPs.

a) The definition of advertising includes “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.” Under FDA policy, “non-promotional” communications such as disease awareness communications are not considered “advertising.”

Labeling is defined as “all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” “Accompanying” has been broadly interpreted to include most types of promotional materials, including brochures, leaflets, catalogues, literature reprints, mailers, printed or digital sales aids, emails, slide decks, videos, websites, and social media posts.

b) The definitions of advertising and labelling apply equally to all target audiences; however, there are separate rules and policies for advertising and promotion depending on the intended audience (e.g., payors, consumers, and HCPs).

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases discussing approved and investigational drugs are permitted. Press releases discussing an approved drug must comply with FDA requirements for promotional labeling, including being truthful and non-misleading, discussing uses that are consistent with the product label, and maintaining fair balance between risks and benefits, including disclosure of relevant contraindications, warnings, precautions and adverse events.

Press releases about investigational drugs, as well as investigational uses of approved drugs, should clearly disclose the investigational status of the drug or use, accurately describe study data, avoid promotional claims or conclusory statements regarding safety or efficacy, and present all material information in a truthful and non-misleading manner.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

It is considered a best practice for companies to adopt internal policies and standard operating procedures to manage the review, approval, and use of promotional labeling and advertising materials. Typically, this process is managed by a cross-functional committee comprised of representatives from the legal, regulatory, medical, and compliance departments within the company.

6. Do companies have to have material approved by regulatory bodies prior to release?

In general, FDA does not approve pharmaceutical advertising and promotional materials before dissemination, except under the following circumstances:

- required pre-clearance of ads following previous violations of FDA or FTC advertising requirements;
- “pre-submission” requirements for prescription drugs approved under FDA’s accelerated approval process; or
- pre-dissemination review for certain categories of direct-to-consumer television ads.

Companies can always voluntarily submit proposed promotional labeling or advertising to FDA for advisory review and comment.

While FDA approval is not required for most drug advertising and labeling, FDA regulations require pharmaceutical companies to submit prescription drug labeling and advertising materials under Form FDA 2253 to FDA’s Office of Prescription Drug Promotion (OPDP) at the time of first use.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative claims regarding a drug’s efficacy or safety are generally permitted if they are based on the approved indication of a drug to the same approved indication of another drug and are supported by scientifically appropriate and statistically sound data (e.g., head-to-head study, clinically relevant to patients, not false or misleading). Comparative claims should not suggest superior efficacy or safety based solely on the differences in product labeling or the results of two different studies.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

The FDCA and FDA regulations prohibit the promotion of unauthorised medicines (i.e., investigational drugs) and unauthorised uses of approved drugs (i.e., off-label uses) as safe or effective.

Despite this broad prohibition, FDA permits certain non-promotional communications about unapproved drugs and indications that are considered "scientific exchange," including support for independent medical education, scientific presentations and publications during scientific conferences, responding to unsolicited requests for information, distributing scientific publications to HCPs, disseminating firm-generated presentations on published, peer-reviewed reprints, publishing information on clinicaltrials.gov, and pre-approval communications with payors.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

"Direct-to-consumer" (DTC) advertising of prescription drugs is permitted provided the communication comports with the following requirements.

- On-label or consistent with label – Consistent with the FDA-approved use of the drug, as established by the drug's FDA-approved labeling (i.e., Prescribing Information).
- Fair balance – Presenting a "fair balance" between presentation of information on product benefits and risks.
- Adequately substantiated (i.e., by substantial evidence, substantial clinical experience, or scientifically appropriate and statistically sound evidence).
- Otherwise truthful and non-misleading.
- Include required information (i.e., proprietary and established names; quantitative composition of each ingredient; "brief summary" in print ads or "major statement" in broadcast ads for side effects, warnings, and contraindications; MedWatch statement).

DTC advertising for OTC drugs must be:

- Consistent with the product's approved labeling (or monograph, as applicable);
- Substantiated by competent and reliable scientific evidence; and
- Truthful and not misleading.

Additionally, FDA strongly recommends that companies use consumer-friendly language in DTC advertising and promotion.

"Reminder" advertising and labeling is exempt from the above requirements. To qualify as a "reminder" ad, the communication must be limited to the drug's proprietary and established names (with other optional information), and must not include any reference to indications, dosage, or other promotional claims. Reminder ads are not permitted for drugs with a boxed warning in the FDA-approved Prescribing Information.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Company interactions with patients, patient organizations, and industry are generally permitted, if they:

- Comply with fundamental advertising and promotion standards (i.e., on-label / consistent with label, fair balanced, adequately substantiated, and otherwise truthful and non-misleading);
- Do not violate the AKS by inducing patients or patient organizations to recommend or use the marketed product;
- Abide by applicable federal and state privacy and security laws; and
- Avoid providing advice for the diagnosis, treatment, care, or prognosis of an individual, which could be regarded as unlawfully engaging in the practice of medicine.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information

about clinical trials, or copies of journal be sent?

The requirements for advertising directed at HCPs are generally the same as those for DTC. If the advertising and promotion to HCPs involves a prescription drug, it must also include adequate directions for use (i.e., Prescribing Information).

However, HCP advertising requirements differ from DTC advertising in slight ways. The “brief summary” for HCP-directed print advertisements should provide the complete risk-related sections of the PI, and there is no requirement to include the MedWatch statement.

In addition, under the FDCA, advertising directed to payors may include healthcare economic information (HCEI) related to a product’s indication, provided that it is supported by competent and reliable scientific evidence and is otherwise consistent with FDA guidance regarding communications with payors.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

The AKS and similar state laws generally prohibit companies from providing gifts of any value with the intent of inducing referrals or other business; however, the PhRMA Code provides some limited protections.

The PhRMA Code allows manufacturers to offer educational items and reimbursements for meals and travel to HCPs in limited situations. Manufactures may provide items that “advance disease or treatment education,” but not items intended for the personal benefit of HCPs, including items of de minimis value (e.g., pens, pads, mugs). Manufacturers may also provide modest meals in conjunction with an informational presentation in the HCP’s office. The PhRMA Code recommends that costs are modest and reasonable, but does not set monetary limits; however, some states establish monetary limits on, or prohibit, these activities.

Importantly, the PhRMA Code is neither law nor regulation. But it is generally recognized as a guideline. Thus, its condoned activities likely pose a lower risk of prosecution under the AKS and similar state laws, while its prohibited activities carry significant risk.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

The Prescription Drug Marketing Act (PDMA) permits a manufacturer to provide samples to licensed HCPs or institutions that request samples, sign for or formally acknowledge receipt, agree to legally prescribe and dispense, and do not resell the samples or bill patients or insurance for them. Samples used as gifts or improper inducements for HCPs to prescribe a particular product could implicate the AKS.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

A company may provide financial support to third parties hosting independent scientific or educational conferences or meetings, including those for continuing medical education (CME). The PhRMA Code specifically notes that the company should develop a policy to ensure that CME grants are bona fide and not an improper inducement.

Companies paying for HCP attendance, travel, or hospitality for such events may violate the PhRMA Code and/or the AKS, unless such payment falls within an established AKS safe harbor.

For events overseas and virtual events, which reach across broader geographies, companies should additionally consider clear disclosures in materials and presentations regarding the intended audience, particularly if the product’s approval status or indication differs outside of the United States.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Sponsoring, financing, or otherwise facilitating participation in cultural, sports, or other non-scientific events by HCPs risks violating the AKS and is also expressly prohibited by the PhRMA Code.

16. Is it possible to pay for services provided by healthcare professionals and if

so, which restrictions apply?

The personal services and management contracts safe harbor under the AKS protects payments for services provided by HCPs provided that:

- There is a written agreement that expressly defines the services to be provided for a term of at least one year;
- The contracted services are commercially reasonable in the absence of other business or referrals generated between the parties;
- The total compensation over the term of the agreement is fixed in advance and consistent with fair market value; and
- The services do not involve any other violation of law.

Services arrangements with HCPs sometimes fail at least one of these requirements. The PhRMA Code provides additional guidance to help protect arrangements that cannot meet the safe harbor protection.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Manufacturers may make grants or donations to HCPs or institutions, but should be aware of the AKS. Such grants or donations, whether monetary or in-kind, generally fall within the AKS's broad definition of "remuneration," and can have consequences if their purpose is related to generating business from the recipient or individuals involved with the recipient, including influencing clinical or purchasing decision-making. To help avoid this, manufacturers often impose guardrails on provision of grants, such as: limit recipients to charitable or non-profit organizations only; fund grants and donations from non-sales and marketing budgets, establish a Grants Committee made up of non-commercial personnel, document each grant and donation (including its intended purpose), and ensure there is no "return on investment" analysis with respect to grants or donations.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

The federal Physician Payments Sunshine Act (Sunshine Act) and its implementing regulations require some pharmaceutical manufacturers (including foreign drug manufacturers that operate in the U.S.) to annually report to the Centers for Medicare and Medicaid Services (CMS) payments or transfers of value provided to HCPs and teaching hospitals during the previous calendar year and ownership or investment interests held in the manufacturer by physicians and their immediate family members. It does not apply to entities that do not have marketed products in the U.S. Several states also require manufacturers to track and annually report certain information about payments or transfers of value provided to certain HCPs and healthcare organizations within their borders. Specific transparency requirements vary from state-to-state.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

Both FDA and FTC regulate advertising and promotion on the Internet under their advertising and promotion rules and guidelines, as well as regulatory guidances specific to the Internet and social media. FDA, for example, has issued guidance documents relevant to use of social media for prescription pharmaceutical promotion that:

- Describe when firms will be held responsible for social media content, including user generated comments (UGC), and how to submit interactive social media to OPDP via FDA Form 2253.
- Explain how FDA's rules regarding disclosure of risk information apply in character-limited communications (e.g., Twitter, sponsored links).
- Explain how companies can address incorrect information posted about their products on social media or the Internet by third parties unaffiliated with the company.

The FTC has also issued guides regarding disclosures on

the Internet and social media.

Neither agency requires companies to include access restrictions on pharmaceutical promotional websites intended for HCPs; however, for HCP-targeted websites, it is common industry practice to include an interstitial page (e.g., pop-up webpage) to confirm the viewer is an HCP.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

The AKS and CMPS arefederal anti-bribery laws applicable to interactions between pharmaceutical companies and HCPs. Many states have similar anti-bribery laws. The Foreign Corrupt Practices Act prohibits bribes or kickbacks in the form of certain payments to foreign (non-U.S.) officials, which in some countries may include government employed HCPs.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The AKS is a criminal law prohibiting individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration to induce the provision of a good or service that is reimbursable under a federal health care program. “Remuneration” includes anything of value (e.g., gifts, payments, discounts or rebates, free or below cost products and services), including items of de minimis value. The scope of the AKS is broad and applies to any individual or entity that provides or receives remuneration—even where the sole or primary purpose is not to provide value for the referral of covered goods or services.

The OIG has promulgated “safe harbor” regulations specifying certain exceptions and several types of arrangements that will not be considered to contravene the AKS (e.g., discounts or rebates, warranties, and employment and services arrangements). If an arrangement satisfies all the criteria of a safe harbor, it will be immune from criminal prosecution and civil exclusion under the AKS. Arrangements falling outside a safe harbor present legal risk that carry both criminal and civil penalties.

Similar to the AKS, the CMPS is a civil law prohibiting the offering or provision of inducements to federal and state healthcare program (Medicare and Medicaid) beneficiaries and impose monetary penalties on entities that offer or transfer remuneration to such a beneficiary when they know or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of covered items or services.

A violation of the AKS or CMPS could also result in a violation of FCA, which prohibits knowingly making a false statement or filing a false claim regarding payment by any federal health care program. The FCA includes a whistleblower provision that allows private citizens to file complaints on behalf of the U.S. Government, which may be based on violations of the AKS, CMPS or FCA.

Some states have enacted their own anti-kickback statutes that apply to inducements related to healthcare items and services (including drugs) reimbursed by private insurance, not just those reimbursed by a federal or state healthcare program.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

FDA and FTC regulate the rules of advertising and promotion through the FDCA, FTCA, and their implementing regulations. Repeat or egregious violations may prompt FDA and FTC to initiate enforcement proceedings in federal court (brought by the U.S. Department of Justice (DOJ)) to enjoin the behavior and seek penalties.

The DOJ and the Department of Health and Human Services Office of Inspector General (OIG) have authority to enforce the AKS, CMPS and FCA. DOJ has authority over both criminal and civil enforcement actions; OIG has authority over civil actions.

State Attorneys General may take enforcement actions under similar state laws, both civil and criminal.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Competitors do not have a right of action under the FDCA or FTCA to challenge unlawful pharmaceutical promotion, but they may submit trade complaints to the agencies to prompt agency enforcement. In addition, companies may directly challenge competitors’ “false and misleading” advertising in court under the Lanham

Act and similar state laws. Competitors may also bring challenges before the National Advertising Division (NAD), a non-judicial, industry self-regulatory body. Companies can also be whistleblowers under the FCA.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Penalties for unlawful pharmaceutical advertising and promotion vary depending on the statute used to challenge the activity.

- For violations of the FDCA, FDA may seize products.
- For violations of the FDCA or FTCA, the government commonly seeks injunctions and may bring criminal charges for more extreme cases.
- For violations of the AKS or FCA, the government may pursue civil penalties (i.e., fines and monetary damages) or criminal sanctions (i.e., monetary penalties or imprisonment).
- For violations of the Lanham Act, the competitor may seek injunctive and/or monetary remedies. More rarely, the competitor may seek a preliminary injunction, disgorgement of profits, treble damages, and/or an award of attorney fees.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

Federal government authorities such as FDA and FTC may pursue enforcement against violative advertising and promotion in federal court. Enforcement by state government authorities occurs in state court. In contrast, enforcement by non-governmental, self-regulatory bodies such as the NAD are not binding in court; however, the NAD may refer certain cases to FTC for potential enforcement.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

Recent regulatory and enforcement trends related to pharmaceutical advertising and promotion include:

1. False or misleading presentation of risk information, which is the most cited violation in FDA enforcement letters.

2. Digital and broadcast advertising and promotional activities, including websites, social media, email, sponsored links, DTC television ads, and radio.

3. Heightened focus by FDA and FTC on patient, HCP, and celebrity spokespeople and influencer marketing.

4. The improper use of HCP speaker programs (e.g., high-end restaurants, serving alcohol, or unnecessary content) raises significant risks under the AKS.

Contributors

Nikki Reeves
Partner
nreeves@kslaw.com

Seth H. Lundy
Partner
slundy@kslaw.com

Heather Bañuelos
Counsel
hbaneulos@kslaw.com

Gillian Russell
Counsel
grussell@kslaw.com