USA

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1 General- medicinal products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

Prescription Drugs

Prescription drug advertising is governed by the Federal Food, Drug, and Cosmetic Act (FDCA) and corresponding US Food and Drug Administration (FDA) regulations.

The FDCA sets out broad requirements for prescription drug advertisements and authorizes the FDA to promulgate related regulations. *See* 21 U.S.C. §352(n). The FDA regulations expand on these general requirements, adding details to the framework set forth in the FDCA. *See* 21 C.F.R. §202.1.

Non-Prescription Drugs

While the FDA regulates the labeling of non-prescription drugs, it does not regulate the advertising; that responsibility rests with the Federal Trade Commission (FTC). Under 15 U.S.C. §§52-57, the dissemination of false advertisements likely to induce the purchase of food, drugs, devices, services, or cosmetics is unlawful and subject to enforcement by the FTC.

1.2 Must advertisements be approved in advance by a regulatory or industry body before use?

Generally, prescription drug advertisements do not need prior approval by the FDA. *See* 21 U.S.C. §352(n). However, in the case of accelerated approval products, all promotional materials (including advertisements) intended for dissemination within 120 days of approval must be submitted to the FDA during the pre-approval period. *See* 21 C.F.R. §314.550. Additionally, in special circumstances, advertisement pre-approval may be required as part of an enforcement action.

While pre-approval is not usually required, all advertisements must be submitted to the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) at the time the advertisement is initially published. *See* 21 C.F.R. §314.81(b)(3)(i). DDMAC will also offer comments on any advertisements submitted prior to publication. *See* 21 C.F.R. §202.1(j)(4).

1.3 What are the penalties for failing to comply with the rules? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

A prescription drug is considered "misbranded" if an advertisement fails to satisfy the requirements of the FDCA and FDA regulations. *See* 21 U.S.C. §352(n). The FDCA prohibits the introduction of a misbranded drug into interstate commerce or the misbranding of a drug already in interstate commerce. *See id.* at §331(a),(b). Potential penalties for misbranding violations include injunction proceedings, civil penalties, seizure proceedings, and even criminal prosecution. *See id.* At §§332-334. The US government is responsible for the enforcement of the FDCA and FDA regulations. *See* 21 U.S.C. 337(a).

Prescription drug advertising is constantly policed by DDMAC. Before pursuing the remedies listed above, DDMAC will often issue a warning letter to the manufacturer outlining any violations and requesting that certain actions be taken, including, in some circumstances, discontinuation of an advertisement.

While the FDCA does not provide for competitors to take action in court, the Lanham Act permits false advertising claims. *See* 15 U.S.C. §1051, et seq. A competitor has standing under the Lanham Act to challenge false or misleading advertising if such competitor believes that it is likely to be damaged. *See id.* at §1125(a)(1)(B).

2 Providing information prior to authorisation of medicinal product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

New drugs cannot be marketed to physicians or other health care providers until they are approved by the FDA. Sharing scientific information, however, is not precluded. Specifically, FDA regulations provide that: "*A sponsor or investigator, or any person acting on behalf of a sponsor or*

investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution." 21 C.F.R. §312.7(a).

Additionally, manufacturers may provide health professionals with information on unapproved uses for already approved drugs so long as the information is in the form of a scientifically sound article or reference publication and it does not pose a significant risk to public health. *See* 21 C.F.R. §99.101(a).

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information on medicines that have not been approved by the FDA may be published so long as the publication is for the purpose of disseminating scientific information or findings. *See* 21 C.F.R. §312.7. Information on unapproved medicines may not be published for promotional or marketing purposes.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

See §§2.1, 2.2 above.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Manufacturers may send information to health professionals about medicines that have not been approved by the FDA if the information is distributed for scientific and not promotional purposes. *See* §§2.1, 2.2 above.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Sending information on an unapproved drug to institutions for budget purposes could be construed as commercializing the drug, which is not allowed under FDA regulations. *See* §2.1 above.

3 Advertisements to health professionals

3.1 What information must appear in advertisements directed to health professionals?

The statutes and regulations governing pharmaceutical advertising do not differentiate between advertisements aimed at health care providers and those aimed at consumers. As a result, the requirements are the same, regardless of the audience targeted by a particular advertisement. For further discussion of what information must appear in pharmaceutical advertisements, see §§6.1, 6.2 below.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison?

Prescription drug advertisements may not be false, unbalanced, or misleading. *See* 21 C.F.R. §202.1(e)(6). Under FDA regulations, a comparator advertisement is false, unbalance or misleading if it: "*Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.*" *Id.* at 202.1(e)(6)(ii).

3.3 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

FDA regulations do not forbid "teaser" advertisements as long as the drug at issue has been approved for marketing by the FDA. For example, FDA regulations allow the use of "reminder" advertisements (which only mention the name of the drug and not its use) and "help-seeking" advertisements (which encourage individuals with a particular condition to see a doctor without mentioning a specific product). *See* 21 C.F.R. §202.1(e).

4 Gifts and financial incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

Drug samples may be distributed to heath care professionals licensed to prescribe the sampled drug. FDA regulations allow samples to be distributed by: (1) mail or common carrier; or (2) direct delivery by a representative or detailer. *See* 21 C.F.R. §§203.30, 203,31. Under either form of distribution, the licensed practitioner must execute a written request and a written receipt. *Id.* When distribution occurs through a representative, the manufacture must conduct, at least annually, a physical inventory of all drug samples in the possession of each representative. *Id.* at §202.31(d). The manufacturer must also maintain a list of all representatives who distribute samples and the sites where those samples are stored. *Id.* at §202.31(e).

Drug samples may not be sold, purchased, or traded. *See* 21 U.S.C. §353(c)(1). However, under certain conditions, drug samples may be donated to a charitable institution. *See* 21 C.F.R. §203.39.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

Offering any type of remuneration directly or indirectly to any person or entity in a position to purchase, lease, order or prescribe (or influence the purchase, lease, order or supply) a service or item reimbursed by a federal health care program could violate the federal Anti-Kickback Statute if one purpose of the payment or gift to the health care professional is intended to induce Federal health care program business. *See* 42 U.S.C. §1320a-7b(b). Pharmaceutical manufacturers must, therefore, carefully scrutinize sales and marketing practices involving gifts, donations or other forms of remuneration that may be given to medical professionals and/or facilities. Certain educational and practice-related items may, however, be

offered to medical professionals under limited circumstances. Pharmaceutical manufacturers should be familiar with the "guidelines" regarding relationships with physicians and other persons or entities in a position to make or influence referrals published by the following three entities: the (i) The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, available online at http://www.phrma.org/publications/policy//2002 04-19.391.pdf; (ii) The HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (may 5, 2003) available online at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf; and (iii) The American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, available online at http://www.ama-assn.org/ama/pub/category/4263.html

Generally, no gift may be given in exchange for prescribing products or a promise to continue prescribing products. Gifts should be primarily for the benefit of patients and of minor value (less than $100). Gifts of *de minimis* value to be used in the physician's practice such as pens and notepads are also allowed. Items intended for the personal benefit of the physician, including cash or cash equivalents, are inappropriate (except as compensation for *bona fide* services). So, for example, gift certificates, tickets to a sporting event, artwork, music, and floral arrangements would be prohibited under all three sets of guidelines.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The Federal Anti-Kickback statute discussed above in §4.2 applies to any remunerative relationship between the manufacturer and a person or entity in a position to generate Federal health care business for the manufacturer. Such persons or entities would also include institutions. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The OIG takes the position that goods and services provided by a manufacturer to a health care professional or institution that reduces or eliminates an expense the provider would otherwise have incurred (e.g., a business operational or overhead expense) implicates the Anti-Kickback statute if the arrangement is tied to the generation of federal healthcare program business. Therefore, manufacturers must refrain from providing any form of remuneration to a health care professional for operational or overhead expenses.

4.4 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

To encourage price competition, the Federal Anti-Kickback statute contains both a statutory exception and regulatory safe harbor for discounts. *See* 42 U.S.C. §1320a-7b(b)(3)(A); 42 C.F.R. §1001.952(h). Both the statutory exception and regulatory safe harbor contain specific conditions that must be met. For example, all discounts must be disclosed and properly reported. Additionally, to qualify under the discount safe harbor, discounts must be in the form of a price reduction and must be given at the time of the sale (under certain circumstances the discount may be set at the time of the sale). *See* 42 C.F.R. §1001.952(h). Notably, the regulatory safe harbor provides that the term "discount" does not include: (i) cash payment or cash equivalents; (ii) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate to this reimbursement methodology; (iii) a reduction in price applicable to one payer **but not** to Medicare or a State health care program; (iv) warranties; (v) services provided in accordance with a personal or management services contract; (vi) routine reduction or waiver of any co-insurance or deductible amount owed by a program beneficiary; or (vii) any other remuneration, in cash or kind, not explicitly described in the regulation. *See* 42 C.F.R. §1001.952(h).

4.5 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

To ensure compliance with the Federal Anti-Kickback statute, no gift or payment should be made contingent on the purchase of medicinal products.

4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed?

The FDCA and FDA regulations do not specifically prohibit the this practice. There is a "warranty" safe harbor in the Anti-Kickback law that excludes certain warranty payments from the definition of "remuneration" under the statute. *See,* 42 C.F.R. § 1001.952(g). The definition of warranty in the warranty safe harbor incorporates the Federal Trade Commission's definition of warranty which includes "any undertaking in writing . . . to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking." 15 U.S.C. § 2301(6)(B). The warranty safe harbor only protects warranties on "items," so, a warranty on a combination of items and services does not technically qualify for protection. Safe harbor protection is available as long as the buyer complies with the standards of 42 C.F.R. § 1001.952(g)(1)-(2) and the manufacturer or supplier complies with the following standards of 42 C.F.R. § 1001.952(g)(3)-(4):

- The manufacturer or supplier must comply with either of the following two standards -- (i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section. (ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately

report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

- The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

5 Hospitality and related payments

5.1 What rules govern the offering of hospitality to health professionals?

Providing "hospitality," such as meals and social functions, to health professionals would also governed by the Federal Anti-Kickback statute. The guidelines set by the, OIG, AMA and PhRMA discussed above in § 4.2 would also be relevant. For example, under the PhRMA guidelines, a Company may hold informational presentations that serve a valid scientific purpose and provide a "modest meal" by local standards. The company cannot, however, provide entertainment or a recreational outing and cannot pay for a spouses' or guests' meal.

The AMA guidelines provide that subsidies for hospitality should not be accepted outside of modest meals or incidental social events held as part of a conference or meeting. *See also, § 5.2.*

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Continuing medical education (CME), professional, and scientific conferences sponsored by third-parties can improve patient care, and as a result, financial support is allowed under the PhRMA, OIG and AMA guidelines in certain circumstances. A manufacturer's financial support may be appropriate if: (i) the subsidy is directly to the conference sponsor; (ii) the sponsor uses the subsidy to create an overall reduction in conference registration fees for all attendees' and (iii) the physician does not receive the subsidy directly. Non-faculty professionals should not be paid for the costs of travel, lodging, or any other personal expenses. A manufacturer may, however, offer financial support to sponsors for modest meals or receptions so long as the meals and receptions are provided for all attendees.

Funding should not, however, be offered to pay for the physician's time associated with attending the conference.

5.3 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

The Federal Anti-Kickback regulations also create a safe harbor for personal services, provided all of the requirements of the safe harbor are met. *See* 42 C.F.R. §1001.952(d). Manufacturers may enter into consulting agreements with physicians so long as the compensation reflects a fair market, commercially reasonable value, and there is a legitimate need for the services. As outlined in the PhRMA guidelines, there are several factors that are relevant in identifying the existence of a *bona fide* consulting arrangement: (i) the agreement is in writing and specifies the nature of the services to be provided and the basis for the payment of those services; (ii) a legitimate need for the services has been identified (and documented) in advance of the request for services and entering into arrangements with prospective consultants; (iii) the criteria for selecting the consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to decide if the consultant meets the criteria; (iv) the number of consultants retained is not greater than the number reasonably necessary to achieve the desired purpose; (v) the company maintains records of the services provided and makes appropriate use of the services provided; (vi) the venue and circumstances of any meeting with consultants is conducive to the consulting services provided and activities related to the services constitute the primary focus of the meeting, with any social or entertainment events clearly subordinate in terms of time and emphasis; and (vii) no payments are made for the consultant's spouse or significant other to attend the meeting.

6 Advertising to the general public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Non-prescription drugs may be advertised to the general public. Such advertising is known as direct-to-consumer advertising (DTC). As discussed above in question 1.1, non-prescription drug advertisements are regulated by the FTC, not the FDA. Federal statutes prohibit the dissemination of false advertisements. *See* 15 U.S.C. §52. This prohibition applies to non-prescription drug advertisements. A "false advertisement" is defined as an advertisement "which is misleading in a material respect." *Id.* at §55. In determining whether an advertisement is misleading, several factors will be considered, including the representations made or suggested by word, design, device, or sound and any material facts omitted.

6.2 Is it possible to advertise prescription only medicines to the general public? If so, what restrictions apply?

DTC advertising is also allowed for prescription drugs. Under FDA regulations, "advertisements" subject to the FDCA fall into two categories, print advertisements and broadcast advertisements. Print advertisements include "advertisements in published journals, magazines, other periodicals, and newspapers . . . ." Broadcast advertisements include "advertisements broadcast through media such as radio, television, and telephone communication systems." 21 C.F.R. §202.1(l)(1). Both types of advertisements shall not be false or misleading and must present a fair balance between the efficacy of a drug and its risks. *Id.* at §202.1. Additional FDA requirements differ slightly depending on the type of advertisement.

Print Advertisements

The FDCA and FDA regulations require that all prescription drug advertisements discussing the effectiveness or indications of the drug must include a brief summary of side effects, contraindications, and effectiveness (known as the "brief summary" requirement). *See* 21

U.S.C. §352(n); 21 C.F.R. §202.1(e). This brief statement must include all risk information contained in the approved labeling, including all side effects, contraindications, warnings, precautions, and adverse reactions. *See* 21 C.F.R. §202.1(e)(3)(iii).

To satisfy the brief summary requirement, manufacturers will usually reprint the relevant sections of the package insert. The package insert is directed at health care providers and may be difficult for consumers to understand. As a result, the FDA has issued a Draft Guidance indicating that it does not intend to object to the use of FDA-approved patient labeling containing consumer-friendly language on contraindications, warnings, major precautions, and frequently occurring side effects. *See* Draft Guidance, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisement, January 2004. Additionally, the FDA has proposed an amendment to its regulations that would require FDA-approved professional labeling to contain a section entitled Highlights of Prescribing Information ("Highlights"). The FDA's Draft Guidance also indicates that the FDA does not intend to object to the use of the information that would appear in the Highlights section to satisfy the brief summary requirement. *See id.*

Two types of advertisements are not subject to the brief summary requirement:

- Reminder Advertisements; and
- Help-Seeking Advertisements.

Broadcast Advertisements

Broadcast advertisements have limitations that print advertisements do not. As a result, broadcast advertisements have different requirements.

First, a broadcast advertisement must include a statement of the most important risk information (known as the "major statement" requirement). Second, a broadcast advertisement must either include a brief summary, as discussed above, or make "*adequate provision . . . for the dissemination of the approved or permitted package labeling in connection with the broadcast presentation*" (known as the "adequate provision" requirement). 21 C.F.R. §202.1(e)(1). In a Guidance Document, the FDA indicated that a manufacturer can satisfy the adequate provision requirement by:

- Providing a toll-free phone number for consumers to call for the approved labeling;
- Referencing a printed advertisement or brochure that can be accessed with limited technology;
- Providing reference to an internet website that contains the requisite labeling; and
- Advising consumers to ask doctors or pharmacists for more information.

See Guidance for Industry, Consumer-Directed Broadcast Advertisements, August 1999.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

While prescription drug advertisements are allowed, a manufacturer may use help-seeking or disease-oriented advertisements focused on raising awareness of a particular condition.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

There is no prohibition on such press releases so long as the drug has received marketing approval from the FDA. In some circumstances, a manufacturer may distribute scientific findings to the lay media prior to approval. *See* §§2.1, 2.2 above.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The FDA has yet to promulgate prescription drug advertising regulations specific to the internet. DDMAC is currently developing a FDA-wide policy to address promotion and advertising of prescription drugs on the internet. *See* http://www.fda.gov/cder/handbook/pol_guid.htm.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

No specific level of security is required. Some prescription drug websites require the health care professional to register while others have no security at all.

8 General- medical devices

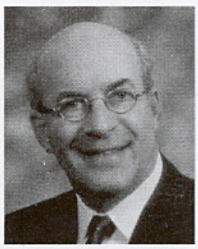
8.1 What laws and codes of practice govern the advertising of medical devices in your country?

Like prescription medications, the FDCA and FDA govern the advertising of restricted medical devices. *See* 21 U.S.C. §352(q),(r). A restrictive device is one in which the sale, distribution, and use of the device must be authorized by a licensed practitioner. Advertisements regarding all other devices are regulated by the FTC.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

The restrictions on hospitality offered to physicians in connection with the promotion of a medical device are similar to the restrictions placed on the promotion of pharmaceutical products. *See* §§4,5 above. There are a few notable differences, however.

The Advanced Medical Technology Association (AdvaMed) has issued its own Code of Ethics on the Interactions with Health Care Professionals specific to medical devices, available online at http://www.advamed.org/publicdocs/code_of_ethics.pdf. AdvaMed developed a code independent of the PhRMA code so that it could address issues specific to the medical device industry. The FDA requires medical device manufacturers to train and educate physicians on the safe and effective use of a particular device. This type of interaction is unique to the medical device context. As a result, medical device manufactures may fund product training and education programs and may provide physicians with hospitality in the form of modest meals and receptions subordinate in time to the training purpose. Manufactures may also pay for reasonable travel expenses and lodging associated with these training programs.



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