

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2008

A practical insight to cross-border Pharmaceutical Advertising work



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1 General - Medicinal Products

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

The federal Food and Drugs Act (the “Act”) establishes the basic criteria for acceptable advertising of drugs and medical devices in Canada. As a general rule, the Act provides that no person shall advertise any drug or medical device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. The Act also sets out a number of more specific rules with respect to certain types of advertising. For example, there is a prohibition against advertising any drug or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A of the Act, which includes a broad list of some 40 conditions deemed sufficiently serious as to warrant this exclusion. Some advertising that is not prohibited is nevertheless restricted under the Act. For example, the Act and its Regulations set limits on the advertising of any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception. The Act is administered by Health Canada.

In addition, the Pharmaceutical Advertising Advisory Board (“PAAB”) is an independent, multidisciplinary body that provides review and clearance of drug advertising and promotional materials. It administers the PAAB Code of Advertising Acceptance (the “PAAB Code”), which applies to advertising of single entity and compound prescription and non-prescription pharmaceutical products, biologicals and natural health products directed at licensed members of most medical and health professions. In theory, compliance with the PAAB Code is voluntary, although compliance is strongly encouraged by Health Canada and required by some industry associations.

Various industry associations have undertaken a host of other self-regulation initiatives. For example, Canada’s Research-Based Pharmaceutical Companies (“Rx&D”), has prescribed a Code of Marketing Practices (the “Rx&D Code”) for its members, and the Canadian Association of Medical Publishers (“CAMP”) has issued Guidelines for General Advertising, Supplied Advertising Inserts, & Journal Supplements (the “CAMP Guidelines”), which apply to all advertising appearing in publications directed to healthcare professionals and pharmacists. These initiatives often cross reference international codes. For instance, the Rx&D Code strongly supports the International Federation of Pharmaceutical Manufacturers Association’s (“IFPMA”) mission and the principles of the IFPMA Code of Pharmaceutical Marketing Practices.

Another independent entity that plays a significant role in the regulation of drug advertising is Advertising Standards Canada (“ASC”), which administers the Canadian Code of Advertising Standards (the “ASC Code”). The ASC Code is not directed specifically at the pharmaceutical industry, but is nonetheless important as Health Canada strongly encourages compliance.

Of course, more general laws regarding advertising also apply. These laws include the federal Competition Act and various provincial consumer protection statutes.

1.2 How is “advertising” defined?

The Act defines “advertising” very broadly to include any representation by any means for the purpose of promoting directly or indirectly the sale or disposal of any drug or device. Health Canada’s Therapeutic Products Directorate (“TPD”) is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. TPD has issued a set of Guidelines entitled The Distinction Between Advertising and Other Activities (the “TPD Guidelines”) to clarify the definition of advertising under the Act. In particular, the TPD Guidelines seek to clarify the distinction between advertising and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labelling and shareholders’ reports). The distinction is drawn by determining the primary purpose of the message. The primary purpose is determined by looking at a variety of factors, including the context in which the message is disseminated, the primary and secondary audiences, the provider of the message, the sponsor of the message, the influence exerted by a manufacturer, the frequency or repetition of the message and, of course, the actual message content.

The ASC Code defines advertising as any message in which the content is controlled directly or indirectly by the advertiser, expressed in any language and communicated in any medium to Canadians (except media originating outside of Canada, and packaging, wrappers and labels) with the intent to influence their choice, opinion or behaviour.

While the codes of other industry associations may not define advertising per se, they typically set out the marketing behaviour to which they apply. The PAAB Code applies to all communications in which claims, quotations and references are made, and provides specific rules for the various defined “Advertising/Promotion Systems”. The CAMP Guidelines apply to any paid message communicated by Canadian media to healthcare professionals and pharmacists. The Rx&D Code adopts the PAAB Code and CAMP Guidelines, and imposes rules regarding a broad range of additional promotional activities.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as “sign off” of promotional copy requirements?

Before the product is advertised, companies must send all pertinent product information (including the product monograph) to all known drug information centres, poison control centres, faculties of medicine and pharmacy across Canada and national medical associations.

As discussed in further detail below in question 1.4 and subject to certain exemptions, companies must submit copies and illustrations for all Advertising and Promotion Systems for prescription drugs intended for distribution to health professionals to either PAAB or ASC (or a Health Canada designated advertising pre-clearance agency) for review and clearance prior to use. A fee for review of materials submitted to PAAB is charged in accordance with a schedule published annually.

Companies must also ensure that promotional materials must not be signed by personnel who work in medical, regulatory or medical/scientific information services, nor by someone who works on their behalf.

Companies that advertise or otherwise promote health care economic studies or pharmaeconomic evaluations that look at the costs and results of alternative therapies must be reviewed and approved by the PAAB following the same approval system that applies to products or services that contain clinical claims.

1.4 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Drug advertisements are reviewed and pre-cleared by ASC and PAAB. Each is an independent entity that is expected to obtain voluntary compliance with certain drug advertising laws and when not obtained the matter can be returned to the TPD, which retains ultimate authority for compliance and enforcement.

ASC reviews advertising material for non-prescription drugs directed to consumers, while PAAB reviews advertisements for all drugs directed to health professionals. In addition, ASC and PAAB also provide advisory opinions on messages directed to consumers regarding prescription drugs to ensure that they meet the regulatory requirements. PAAB requires that the sponsor’s medical/regulatory department approve all advertising prior to sending it to PAAB for approval.

Although use of these pre-clearance regimes is not mandatory, it is strongly encouraged by Health Canada. In practice, most manufacturers view this as a de facto requirement.

1.5 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

PAAB may withdraw clearance at any time and request suspension of publication if a complaint to PAAB has been upheld, medical advice suggests the advertisement may constitute an imminent or significant health hazard, new significant information has come to light, or there has been an error or omission of fact. PAAB must provide a written letter to the advertiser detailing the rationale for

withdrawal of clearance and a schedule setting out by what date use of the material is to cease. A decision to withdraw clearance may be appealed to a PAAB review panel. The PAAB Code outlines the appeals process.

1.6 What are the penalties for failing to comply with the rules governing the advertising of medicines? 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?

Failure to comply with the legislative requirements for drug advertising in Canada is a criminal offence, punishable by up to three years’ imprisonment and/or a fine of up to \$CDN 5,000. The Minister of Health is responsible for enforcing the Act. In practice, criminal enforcement of the rules is infrequent in light of the Minister’s power to refuse drug licences or otherwise create regulatory difficulties for non-compliant drug manufacturers.

Various industry codes provide mechanisms for the resolution of complaints between competing manufacturers. Sanctions for violations of the PAAB Code may include a direction to publish corrective notices in annual reports or newsletters, or to issue public letters of apology. Violations of the Rx&D Code will be published in the Rx&D Update newsletter and subject to a fine of \$CDN 10,000/15,000/25,000 for the first/second/third violation, respectively, within a twelve-month period. Upon the third violation, the Chief Executive Officer of an offending company will also be required to appear before Rx&D’s board of directors. Each additional violation after the third one results in publication of the infraction in the Rx&D Update and a fine of \$CDN 50,000. Compliance with sanctions is a condition of continued membership.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

Though self-regulatory organisations assume responsibility through Health Canada’s endorsement, Health Canada retains ultimate regulatory authority with respect to the Act and its Regulations. While Rx&D is a strong self-regulator independent of Health Canada, the processes of PAAB and ASC are especially informed by the supervisory and enforcement powers of the federal supervisory and enforcement mechanism. For instance, the TPD acts as an advisor to PAAB and is an ex-officio observer on PAAB’s Board of Directors. Also, Health Canada has access to the complaints and appeals procedures under the PAAB Code and ASC Code. The flow of information between Health Canada and the advertising review organisations is outlined in the Health Canada policies titled Drugs Directorate and the Pharmaceutical Advertising Advisory Board and Advertising Standards Canada and Health Canada’s Roles and Consultation Related to Advertising Review and Complaint Adjudication.

The underlying principle behind Health Canada intervention or involvement is a perceived breach of the Act and Regulations. With respect to the advertising pre-clearance process, Health Canada will review advertisements when they contravene the Act and Regulations and may present an imminent or significant health hazard, or when the contravening advertising arises from a failure

of the self-regulatory system as a result of wilful non-participation or non-compliance with the PAAB or ASC Codes. PAAB and ASC are expected to refer such matters to Health Canada. Even if advertising materials are approved by PAAB, the TPD can ask that they be held back and not used if the TPD is concerned that the materials pose a health threat under the Act or its Regulations.

The same principles apply to the self-regulatory complaints and appeals processes. PAAB and ASC will bring complaints to the attention of Health Canada where, in the judgment of the self-regulatory body, the complaint relates to advertising that contravenes the Act and Regulations and presents an imminent or significant health hazard, or contravenes the Act and Regulations and the self-regulator has been unable to bring about compliance (again, through wilful non-participation or non-compliance with the self-regulatory system). Complaints concerning the promotion of unapproved drugs are sent to Health Canada for investigation should they be sent to a self-regulatory body in error. Issues raised for consultation with Health Canada are limited to claims or attributes that would require pre-market review and authorisation.

1.8 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Features of drugs, such as their colour and shape, are entitled to protection under the law. An action for unfair competition may be brought under the common law action of passing off, or under the Trade-marks Act. Individuals, trade associations and companies may have standing to initiate legal proceedings for unfair competition.

The Supreme Court of Canada has noted that competing laboratories must avoid manufacturing and marketing drugs “with such a similar get-up that it sows confusion in the customer’s mind”. Nevertheless, in order to be entitled to protection it is necessary to show that the “trade dress” has acquired “secondary meaning”, and that the unauthorised use of a similar trade dress has caused or is likely to cause confusion. In addition, it may be necessary to defend the trade dress against an attack that it is functional or offers a safety advantage. Manufacturers may argue that an overriding concern with respect to the colour, shape and size of a drug is safety, and that making drugs look similar as opposed to distinct is actually an advantage for pharmacists and patients.

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?

Advertisement of a drug before it has been approved for the Canadian market is prohibited by the Regulations to the Act. The prohibition is not, however, intended to impede the free flow of information within the scientific community. The TPD Guidelines establish criteria for distinguishing between “promotional” activities and “non-promotional” activities. Information regarding unauthorised medicines may be presented and freely discussed at scientific meetings, provided that such meetings constitute “non-promotional activities”. The distinction between promotional and

non-promotional activities is generally dependent on the nature of the particular activity, the probable audience and the extent to which the activity is intended to promote the sale of a drug.

For example, scientific meetings may be considered non-promotional where there is no ancillary commercial or promotional activity relating to drug products and discussion of an unauthorised drug includes a statement indicating that the drug has not been authorised for the Canadian market. Where a pharmaceutical manufacturer sponsors the meeting, the sponsor is prohibited from influencing the content of the agenda or the content of any presentation (where it concerns a drug manufactured by the sponsor). Also, a manufacturer must fully disclose the nature of its sponsorship role.

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

Information concerning unauthorised medicines may be published in reference texts, peer-reviewed journal articles and government publications. Such publications will constitute non-promotional activities only where no link can be established between the text and promotion of the drug. In addition, the manufacturer of the drug is prohibited from influencing the writing or editing of the publication and summarising or interpreting the published material.

Manufacturers may also sponsor the publication of a journal supplement, which is usually a collection of related articles, provided as a separate issue or second part of a journal. Sponsorship of such a publication, in whole or in part, may constitute a “non-promotional” activity where:

- the insert consists of unedited symposium proceedings which address issues relating to a variety of diseases or drug treatments;
- the insert discusses various treatment approaches for the same medical condition;
- the publication specifically targets health professionals or the scientific community;
- there is no obvious link between the drug discussed and the identity of the pharmaceutical manufacturer that sponsors the supplement; and
- the supplement is clearly distinct from the regular journal edition.

Failure to meet one or more of the conditions listed above may result in a supplement being construed as advertising. Pharmaceutical manufacturers must also take care in restricting their influence over the content and circulation of a sponsored supplement. Journal supplements that are disseminated or edited by their sponsors may be considered advertising. In addition, placement of a conventional advertisement for a drug product within close proximity of an article discussing the unauthorised use of the same drug product may constitute advertising.

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

In Canada, it is common practice for pharmaceutical manufacturers to release information to the press concerning new research developments or the introduction of a new drug to the market. As with scientific meetings and publications, to avoid being subject to advertising regulations, such press releases must constitute “non-promotional” activities. To be considered “non-promotional”, the contents of a press release must be limited to: the name of the drug, its proposed therapeutic use, and a statement that the safety and

efficacy of the drug is still under investigation and that market authorisation has not been obtained. In addition, the announcement must be directed at shareholders or potential shareholders. Where a manufacturer provides a press release to another targeted audience (e.g., physicians), the press release may be considered advertising.

Manufacturers are also prohibited from making statements regarding the degree of safety or efficacy expected from the drug or making comparisons with other treatments. Undue emphasis on the therapeutic benefits of the drug and hyperbolic descriptions of the drug as a “breakthrough” may be considered advertising. Finally, manufacturers may not influence the placement, visibility or emphasis of their announcement in subsequent publications. Any fees paid by a manufacturer to have a message published or broadcast will factor into the message’s ultimate characterisation as advertising.

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

Information, including material concerning unauthorised products, may be provided to a health professional by a pharmaceutical manufacturer, only where the information has been requested by the health professional. Manufacturers are prohibited from soliciting such requests.

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?

Institutions seeking information for budgetary purposes are limited to sources detailing a pharmaceutical manufacturer’s philosophy, activities, product range (by name), financial details and areas of future research and development. The pertinent information may be found in the manufacturer’s brochures, published articles, prospectuses and annual reports. Any references to a drug product must be limited to the name and therapeutic use of the product and no emphasis may be placed on that product. Dissemination of such information will be considered a “non-promotional activity” where the clear purpose of the communication is to provide information about the manufacturer’s company and not the drugs being marketed, researched or developed. Information provided by the manufacturer in response to an unsolicited request is also considered a “non-promotional activity”.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Subject to the following limitations set out in section 12 of the RX&D Code, companies may involve health professionals in market research exercises prior to the authorisation of medicinal products:

- the purpose of the individual or group interview must be made clear to the participants;
- market research must not be a disguise for selling or developing sales contacts and must not deliberately sway the opinions of the participants;
- fees offered to health professionals who gather or provide market research information should be based on rates similar to and not higher than their usual rate of pay;
- the company organising the market research must preserve

the confidentiality of the participants and this cannot be waived through the consent of the participants;

- the identity of the participants must not be revealed for purposes of promoting the Company’s products to them in the future;
- direct contact and administration with the participants in the market research project should be limited to marketing research personnel only with no sales representative involvement;
- there should be no follow-up by sales representatives derived specifically from the market research contacts;
- the market research questionnaire or program should not be designed in a manner that could be interpreted to be leading to a specific product conclusion;
- health professionals should not be provided with any promotional materials during market research meetings; and
- companies must separate market research from other types of activities.

3 Advertisements to Health Professionals

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

The PAAB Code requires that all pharmaceutical advertising directed to health professionals include the following:

- the brand or trade name of the drug;
- the non-proprietary (generic) name of the drug;
- the federal drug schedule of the drug; and
- the therapeutic and/or pharmacologic classification of the drug.

3.2 Is it a requirement that there be data from any or a particular number of “head to head” clinical trials before comparative claims are made?

There is no specific minimum number of clinical trials required to support a comparative claim, but such claims are subject to general and industry specific advertising laws and guidelines. A comparative claim must be supported by adequate and proper testing concluded before the representation is made. Furthermore, claims regarding the therapeutic aspects of drugs must be based on testing that has considered all relevant data and is scientifically accurate, unbiased, reproducible, and in line with current scientific standards using established research methodologies and validated end points. While the question is fact-specific, it seems unlikely that a comparative claim could meet the required standards without having conducted head-to-head clinical trials.

3.3 What rules govern comparator advertisements? Is it possible to use another company’s brand name as part of that comparison? Would it be possible to refer to a competitor’s product which had not yet been authorised in Canada?

Comparative claims are governed by a Health Canada policy entitled Principles for Comparative Claims Relating to the Therapeutic Aspects of Drugs. The PAAB Code adopts and adds to this policy, setting out a comprehensive list of rules. The PAAB Code provides that comparative claims must acknowledge competitors’ trade-marks.

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The Rx&D Code permits the distribution of scientific and medical papers to health care professionals at conventions and clinic displays, provided they are reprinted verbatim and not presented in a manner which differs in any way from the official product monograph.

3.5 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)?

PAAB has issued guidelines entitled Administrative Guideline for the Review of Pre-NOC Advertising Submissions, which note that under PAAB’s mandate it can only provide acceptances for advertising that will be disseminated after a notice of compliance has been granted. PAAB will not issue acceptances for any promotional activities carried on prior to authorisation, such as “teaser advertising”. However, there is no clear delineation of the scope of such “teaser advertising”, nor any express prohibition provided a product is not specified.

4 Gifts and Financial Incentives

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

The Regulations to the Act permit the distribution of product samples to registered physicians, dentists, veterinarians, surgeons or pharmacists provided that (a) the drug is not a narcotic, a controlled drug or a drug that is not yet approved; and (b) the drug is labelled in accordance with the Regulations. In addition, whenever a manufacturer distributes a sample of a drug, it must also maintain (and keep for a period of at least two years) records showing (a) the name, address and description of the sample recipient; (b) the brand name, quantity and form of the sample distributed; and (c) the date upon which the sample was provided.

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

The provision of gifts or donations to medical practitioners is governed by both manufacturer-side and practitioner-side codes of conduct and guidelines.

On the manufacturer side, the Rx&D Code states that member companies must not offer to any healthcare professional, or to any member of a healthcare professional’s clinical/administrative staff, any gift (in cash or in kind), or any promotional aid, prize, reward, or any other item which is intended for personal/family benefit, or pecuniary advantage. The Rx&D Code also contains restrictions relating to donations, hospitality and service-oriented items provided to medical practitioners.

On the practitioner side, in addition to guidelines issued by provincial regulatory bodies such as The College of Physicians and Surgeons of Ontario, provincial regulations address this issue. In Ontario, for example, the Health Professions Procedural Code and the Professional Misconduct Regulation state that accepting any benefit or gift, whether direct or indirect, could lead to a conflict of interest that may result in the medical practitioner committing an act of professional misconduct.

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?

Hospitals, like medical practitioners, are regulated provincially. Provincial regulations generally do not prohibit either the giving of gifts or donations of money, or donations of equipment and funding for medical or technical services, to institutions such as hospitals. However, the provision of such benefits should be made to the institutions themselves, and not to healthcare professionals employed by such institutions. Otherwise, the restrictions discussed above at question 4.2 may apply.

In addition, section 426 of the Criminal Code (Canada) prohibits hospital employees from corruptly accepting benefits in order to act contrary to the interests of their employer. Acceptance and/or provision of such “secret commissions” is a criminal offence punishable by imprisonment of up to five years.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

The provision of medical or educational goods and services to health care professionals is generally allowed, provided that the goods and services do not amount to promotional efforts. Under section 11 of the Rx&D Code, the provision of service-oriented items is not prohibited, so long as their distribution is not carried out for product promotional purposes. Any such service is disallowed if it could not be justified if subjected to scrutiny by members of the health professions and the public. “Acceptable” service-oriented items are defined as those whose primary goal is to enhance the health care professional’s or patient’s understanding of a condition or its treatment. A corporate logo or name is allowed, but an item must not bear the name of any medicine. If a promotional purpose were suspected, an objection could be launched in the form of a complaint to the Industry Practices Review Committee (IPRC) under the enforcement mechanism of the Rx&D Code. A potential increase in market share or market expansion would have to relate to an underlying promotional purpose in order to hold up as a sound objection to the item in question.

It should also be noted that if an educational or service-oriented effort amounts to paid advertising, it must be cleared with PAAB. Editorial materials that are objective, balanced and scientifically rigorous, as well as unrelated to any particular product, must still be submitted to PAAB for review and clearance if it amounts to a paid advertisement. In any event, such a form of advertising (i.e. editorial/educational) should not be tied to promotional claims.

4.5 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?

Canadian federal antitrust/competition legislation generally prohibits volume-related discounts to institutions that are in potential competition if such discounts have the effect of lessening competition. Canada’s Competition Act requires that volume-related discounts be offered to each customer of the manufacturer on the same terms.

Provincial laws also govern the permissibility of offering volume-related discounts to institutions purchasing prescription drugs. For example, Quebec prescription drug insurance laws prohibit such products from being given without consideration or sold by manufacturers or wholesalers to buyers with a rebate, discount or premium. Similarly, Ontario law prohibits manufacturers from giving rebates to, or accepting rebates from, wholesalers and pharmacies. (For details, see the discussion of Ontario's Transparent Drug System for Patients Act in question 9.1 below.)

4.6 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?

The Competition Act governs whether additional medical or technical services or equipment can be offered or paid for where such offer is contingent on the purchase of other medicinal products. The Competition Act prohibits manufacturers from engaging in "tied selling", which is defined as a practice whereby a supplier (a) requires a customer as a condition of supplying product or (b) induces a customer by offering better purchase terms, to either purchase another product from the supplier or refrain from using another product that is not the supplier's. In addition, to the extent that a manufacturer has customers who may be in competition with each other, the Competition Act requires the manufacturer to offer the same benefits on proportional terms to each of those customers.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The licensing standards for drugs (whether prescription or over-the-counter) require that they be effective and safe. If the product is not effective or safe, it must be recalled. Currently, there are no laws or regulations prohibiting the offer of refunds for recalled products.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Pharmaceutical companies may sponsor continuing medical/health education (CME/CHE) events, subject to various Rx&D Code restrictions. Among these restrictions, member companies must not be involved in the development of or payment for social functions conducted in conjunction with the event. In addition, sponsorship recognition must be limited to "service oriented items" whose primary goal is to enhance the health care professional's/patient's understanding of a condition or its treatment. Service oriented items may bear the donor's corporate name and logo, but not the name of any medicine.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

Health professionals in Canada are governed by a variety of provincial statutes and regulations, along with policies and ethical

codes established by each profession's regulatory body. Most ethical codes place general constraints on a health professional's ability to participate in activities which call into question their professional integrity. Such activities may include accepting inappropriate offers of hospitality. In several Canadian jurisdictions, including Ontario, breach of ethical codes of conduct will constitute an act of professional misconduct, which may be subject to disciplinary proceedings.

Pharmaceutical manufacturers that offer hospitality to health professionals are subject to the Rx&D Code (if they choose to be a member), which provides that the only form of acceptable hospitality are refreshments or meals which are modest in content, and are clearly incidental to the meeting between health professionals and industry representatives. In addition, manufacturers are barred from extending any hospitality to spouses of health professionals, unless the spouse is also a health professional. A maximum of five health-care professionals is permitted per event, regardless of the number of Rx&D members present.

Limitations on acceptable hospitality also apply to hospitality that will take place outside of Canada. This position is confirmed by the World Medical Association's policy statement entitled, *The Relationship Between Physicians and Commercial Enterprises*. The policy limits hospitality to "what is locally customary and generally acceptable".

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?

All provincial regulatory authorities allow physicians to accept reasonable honoraria and reimbursement for travel, lodging and meal expenses for speaking at or moderating scientific meetings or CME/CHE events. However, most Colleges prohibit non-participating physicians from accepting travel, lodging or personal expenses associated with simply attending a scientific meeting.

Similarly, the Rx&D Code allows pharmaceutical manufacturers sponsoring scientific meetings or CME/CHE events to provide physicians who speak or moderate at such events with grants and honoraria. Any such payments must be restricted to the physician and may not be extended to spouses or family members of the participating physician. They may also not be paid to physicians merely attending the programme.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

The Rx&D Code provisions concerning Continuing Health Education (CHE) apply to member companies as well as third party organisers. The specific content of a CHE programme must be developed by consensus among the member(s) and their CHE partner(s). The content of such a programme or meeting must reflect a professionally accepted understanding of what constitutes the 'basic health sciences, clinical sciences and clinical practice of the professions'. Under the PAAB Code, materials created by the academic organisers of a continuing education event do not amount to advertising if distributed at the event or, at a later date, to

registrants of the same meeting. A sponsor company that distributes such materials after the event to non-participants must submit the material to PAAB for review where the material contains product or therapeutic claims, comparative data or statements regarding the sponsor company's products.

According to the Rx&D Code, a member company should not be involved in developing or paying for social functions conducted in conjunction with such an event. Hospitality arrangements are acceptable where limited to modest meals and refreshments, which may not be extended to the spouses or companions of health care professionals (unless they are also a health care professional). (See question 5.1 above.)

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

All provincial regulatory authorities allow physicians to accept fees for services rendered, provided that such services are not a disguise for gifts or donations. For example, the Regulations to Ontario's Medicine Act provide that receipt of any fee for services rendered by a physician, will be a conflict of interest if it cannot be evidenced by a written contract. Conflicts of interest are considered acts of professional misconduct and may result in disciplinary proceedings against the conflicted physician.

The Rx&D Code allows manufacturers to offer an honorarium to physicians who participate in market research for a pharmaceutical manufacturer. The amount of the honorarium is limited to an amount calculated based on the physician's usual rate of pay. In addition, pharmaceutical manufacturers which conduct market research must ensure that the market research is not a disguise for selling or developing sales contacts and must refrain from attempting to sway the opinion of participating physicians.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

Physicians may be paid for their participation in post-registration clinical studies provided the pay reflects costs incurred in conducting the study, such as salaries of study staff and expenses for laboratory tests. Payments may be in the form of a monetary grant, travel to attend scientific and medical meetings, or provision of equipment needed for and relevant to the study. Payments must not be based on continuing administration of the medicine to patients after the study protocol has been completed.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

The use of promotional materials is limited to service oriented items, as discussed above.

Pharmaceutical companies may seek the advice and guidance of physicians on any number of issues, including product development and marketing. There must be a written agreement confirming the purpose, objectives and nature of the consultation services to be provided. Remuneration must be in the form of a fair and reasonable honorarium, in addition to any warranted reimbursements for reasonable travel, accommodation or other out of pocket expenses incurred in providing the consulting services. Honoraria offered to physicians who gather to provide market research information should be based on rates similar to, and not more than, their usual rate of pay.

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, but such advertisements are subject to the Act and the various other codes, guidelines and laws discussed above. Health Canada has introduced proposals to relax certain restrictions with respect to non-prescription drug advertising, but no formal regulatory amendments have been passed. (See discussion in question 9.2 below.)

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

Advertising of prescription drugs to the general public is permitted in Canada, although very stringent rules are imposed under the Regulations to the Act. Such drugs, known in the legislation as "Schedule F" drugs, may not be advertised to the general public other than with respect to the brand name, proper name, common name, price and quantity of the drug. Furthermore, the Act prohibits any advertising to the general public of drugs as a means to prevent, treat or cure conditions listed in "Schedule A" of the Act. There are currently 40 conditions listed in this schedule including alcoholism, anxiety, cancer and heart disease. The Act also prohibits the distribution of a drug as a sample, except in the case of distribution to designated health care professionals (such as doctors and pharmacists). Finally, the Act makes it an offence to advertise a drug in a deceptive manner.

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?

Although Canadian drug advertisers are required to limit their advertising to the basics of brand name, proper name, common name, price and quantity (often called "reminder" ads), there is no prohibition against publicising purely "informational" pieces that detail particular health conditions or illnesses. Such "help seeking" messages invite consumers to ask their physicians about new, unidentified drug treatments for identified symptoms or disease conditions. However, these messages cannot be linked to a specific product, and an advertising campaign will be considered as a whole. Thus, advertisers must be careful not to reveal their sponsorship of the "informational" ad, directly or by including similar themes, characters or other identifiable aspects which link the informational ad with a "name, price, quantity" ad.

In addition, patient support groups often publish information in the form of brochures that are intended to promote a better understanding of a disease and its treatment. As discussed, the definition of "advertising" under the Act is very broad and must be considered in light of the primary purpose of the message in question. Brochures may include specific drug information yet retain their non-promotional status under the following conditions set out in the TPD Guidelines:

- the overall content is disease-related rather than product-related;
- the various treatment options (drug and non-drug) and their respective risks and benefits are discussed in an objective manner;

- no emphasis is placed on a single drug product or its merits;
- no reference is made to an unauthorised drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorisation not yet obtained); and
- no reference is made to the availability of unauthorised drugs through the Special Access Program. Patient support group publications may be advertising where any of the above conditions are not met, and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

Biological and radiopharmaceutical drugs listed in Schedules C and D of the Act are not subject to the same stringent advertising-to-the-general-public restrictions as prescription-only drugs even though they are generally prescribed treatments. For example, a vaccine to prevent the flu can be advertised as such while an antiviral prescription drug to treat the flu cannot.

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

The TPD Guidelines note that it is common practice for a pharmaceutical manufacturer to release information on new developments in various stages. For example, manufacturers may wish to issue press releases while in research and at the time of launch of a new drug or a new indication for use of a previously authorised product. A press release or information disseminated at a press conference concerning a drug may be a “non-promotional” activity (thus allowing mention of prescription-only drugs beyond that allowed by regulation) in the following circumstances:

- the announcement is directed to shareholders or potential shareholders;
- the announcement is limited to the name of the drug and its authorised or proposed therapeutic use;
- no statement is made regarding the degree of safety or efficacy expected;
- no comparison is drawn with other treatments;
- in the case of unauthorised drugs, or unauthorised indications, the message cautions that the safety and efficacy are still under investigation and that market authorisation has not yet been obtained; and
- there is no attempt to influence the pick-up, placement or emphasis given in subsequent publication or broadcast.

In contrast, a press release or information disseminated at a press conference may be advertising where any of the above conditions are not met, or where other factors indicate that the primary purpose of the message is to promote the sale of a drug, for example:

- undue emphasis is placed on the drug being a “breakthrough”;
- the press release is subsequently sent or provided to another audience, e.g., mailed to physicians;
- a fee is paid by the sponsor to have the message published or broadcast; or
- in the case of an unauthorised drug, it is indicated that the drug is available through the Special Access Program.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Where an institution describes products and research initiatives in corporate brochures and annual reports, such messages are subject to the Act, the industry codes and guidelines discussed above,

unless they do not promote the sale or disposal of a drug. Information in brochures and annual reports generally constitutes a non-promotional message where:

- the purpose of the communication is clearly to provide information about the institution rather than about the drugs being marketed, developed or researched;
- information about the drugs being marketed, developed or researched is limited to the name and therapeutic use of the drug; and
- no emphasis is given to any one or more products, or their benefits.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The RX&D Code provides that its members must ensure that the funding of organisations, such as patients support groups, is not for product promotional reasons and is not directed to product promotion purposes. Acknowledgment of funding made by a patient support group must be restricted to an appropriate statement of support, the corporate name and logo of the donating member.

7 The Internet

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

Internet advertising in Canada is regulated in essentially the same way as traditional advertising. Both are subject to the myriad of laws, regulations and codes already described above. The Federal Competition Bureau has issued an Information Bulletin entitled Application of the Competition Act to Representations on the Internet which provides guidance to advertising on-line generally. Also, various Internet-specific industry standards have been adopted and continue to evolve as the need for clarification arises. Further, the PAAB Code prescribes standards for appropriate advertising on the Internet, with specific rules for practices such as pop-ups, links and chat rooms.

However, the Act and the various industry organisations (such as PAAB and Rx&D) only have jurisdiction over companies operating in Canada and directing advertising to Canadians. PAAB has issued an advisory entitled Internet Advertising - An Ethical Guidance (the “PAAB Internet Advisory”), which highlights the limitation of the PAAB Code’s reach to Internet advertising on websites originating in Canada and controlled by Canadian pharmaceutical companies. Indeed, ASC specifically excludes from its mandate advertising communicated by any media that originates outside of Canada. As a result, there is effectively no control over Internet advertising of pharmaceutical products originating in other jurisdictions (except by their home jurisdiction’s rules, if any).

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?

The PAAB Internet Advisory provides that information or advertising on a website that is directed at health professionals should be identified as such. The following suggestions are provided:

- use passwords to ensure that non-professionals cannot gain access to the restricted information;

- do not promote the site to the general public;
- refrain from providing keywords for search engines that draw non-professionals to the site; and
- use appropriate subject matter and terminology to make it clear that the content of the site is directed to health professionals as opposed to the general public.

Linking to other websites is permissible provided it does not appear to be in promotion of the sale of a Schedule F Drug. The PAAB Internet Advisory cautions that Health Canada officials consider this to be a grey area, although an example of a permissible link is provided: "For U.S. Company X Web-site click here". This is contrasted with an impermissible link: "For information on brand X click here".

The PAAB Internet Advisory also notes that it may be permissible for a pharmaceutical company to place complete Health Canada-approved Product Monographs on a company's website in a manner that provides the Product Monograph as information rather than advertising.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Company sponsored websites can provide links to independent websites provided that it does not appear that the company is promoting the sale of a Schedule F drug. The Competition Act, Food and Drugs Act and Regulations, RX&D Code and the PAAB Code apply to pharmaceutical product advertising intended for health professionals and placed on internet websites that originate in Canada and are controlled by Canadian pharmaceutical companies.

Whether the company will be responsible for the content of the independent website would need to be considered on a case-by-case basis. According to the Information Bulletin on the Application of the Competition Act to Representations on the Internet, the Competition Bureau will focus on the party who causes the representation to be made considering the nature and degree of control that the person who makes a representation exercises over the content. A person who merely prints, publishes or otherwise disseminates a representation including an advertisement on behalf of another person in Canada may claim protection under the so-called "publisher's defence" provided that person: (a) does not have decision-making authority or control over the content; (b) accepted the representation in good faith and in the ordinary course of business; and (c) recorded the Canadian-based advertiser's name and address.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The information posted on a pharmaceutical company's website must conform with the requirements of the Food and Drugs Act and Regulations. Companies may not promote the sale of a prescription drug except for name, price and quantity or advertise a drug for a prevention, treatment or cure for Schedule A drugs. PAAB provides an advisory service on whether or not the information about prescription drugs would be considered advertising.

Companies may also place the complete Health Canada approved Product Monographs on the website in a manner that provides the Product Monograph as information rather than advertising.

8 General - Medical Devices

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

The Medical Devices Regulations of the Act regulate all aspects of medical devices in Canada. For instance, medical devices sold or imported into Canada must meet detailed labelling requirements. Also, advertising for certain medical devices may require a licence with respect to that device or a clear and visible warning that the device may not be licensed in accordance with Canadian law. Other provisions in this Regulation parallel the restrictions relating to advertising of non-prescriptive drugs.

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

The main industry association, Canada's Medical Device Technology Companies ("MEDEC"), has issued a Code of Conduct on Interactions with Healthcare Professionals (the "MEDEC Code of Conduct"). In light of parallel developments in the United States and complementary guidelines issued by Rx&D and the Canadian Medical Association, the MEDEC Code of Conduct was introduced to promote ethical business practices and socially responsible industry conduct to govern its members' interactions with health professionals.

The MEDEC Code of Conduct:

- applies to member-sponsored product training and education programmes;
- introduces principles guiding support for third-party educational conferences;
- sets out guidelines for inviting health professionals to sales and promotional meetings;
- regulates to what extent members may pay health professionals for consulting services; and
- establishes a modest threshold (\$CDN 100) for gifts to health professionals.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

PAAB introduced new fair balance/disclosure requirements to change the way prescribing information is presented in print advertisements. The goal of such requirements is to redistribute the mass of small-type footnotes on the main display area of the advertising.

All APS submitted to the PAAB for review now needs to be reviewed by either a medical or regulatory representative of the company to ensure accuracy with the terms of market authorisation by Health Canada and that the references in the advertisement meet PAAB Code requirements.

As of January 1, 2008, all companies must use a web-based electronic file submission software system to submit new advertising files for review by the PAAB.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The federal government appears to be focused on passing new pharmaceutical safety legislation but it is a minority government. So it is unclear whether there will be any significant developments in the field of pharmaceutical advertising in the next year.

A new federal Bill was recently tabled that will result in an expedited drug licensing review process (including post-authorisation safety monitoring in the market) and allow the federal government to make mandatory recalls of unsafe products, including pharmaceutical products. If the Bill is passed, Health Canada will have authority to be more proactive in informing the pharmaceutical industry about its obligations, manufacturing standards for consumer products will be more stringent and industry will be required to report any injuries, near misses or product defects.



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9.3 Are there any general practice or enforcement trends that have become apparent in Canada over the last year or so?

Off-label representations appear to be a source of a number of complaints to the PAAB and it will be interesting to see if there are any changes to the PAAB Code to address when/how off-label representations can be made.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

No. Canada is not a member of EFPIA.



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