Chapter

Canada

DLA Piper (Canada) LLP

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 “FDA”) establishes the main regulatory framework and provides the basic criteria for the lawful advertising of drugs in Canada. As a general rule, the FDA provides that no person shall advertise any drug 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 FDA also sets out, in part through the listing of drugs in various Schedules, more specific rules with respect to advertising certain types of drugs – namely:

1. There is a prohibition against advertising drugs on the Prescription Drug List 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 FDA, which includes a broad list of conditions deemed sufficiently serious as to warrant this exclusion (including acute anxiety state, asthma, cancer, congestive heart failure, depression, diabetes and hypertension). There is also a prohibition against advertising the following drugs to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states deemed sufficiently serious as to warrant this exclusion (including acute anxiety state, asthma, cancer, congestive heart failure, depression, diabetes and hypertension).

2. “Schedule D” drugs (i.e., “biologics” manufactured from animals or microorganisms which include vaccines/immunising agents, blood and blood components, and gene therapies);

3. so-called “ethical” drugs (i.e., drugs that under the FDA do not require a prescription but that are generally prescribed by a medical practitioner (such as a few emergency use products like nitroglycerine) and certain unscheduled, non-prescription, professional use products like MRI contrast agents and hemodialysis solutions); and

4. so-called “non-prescription” or “unscheduled” drugs (i.e., over-the-counter (“OTC”) drugs) and natural health products (“NHPs”) which include vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, and other products like amino acids and essential fatty acids;

2. As discussed more fully in question 6.2 below, direct-to-consumer (“DTC”) advertising of prescription drugs is limited to name, price and quantity; and

3. As discussed more fully in question 6.1 below, DTC advertising of OTC drugs and NHPs is also subject to the detailed guidelines in the Consumer Advertising Guidelines for Marketed Health Products (“CAGs”).

Furthermore, some advertising that is not prohibited is nevertheless restricted under the FDA. For example, the FDA and its Regulations set limits on the advertising of any drug manufactured, sold or represented for use in the prevention of conception.

The federal Controlled Drugs and Substances Act (“CDSA”) and its Regulations set out further rules specific to advertising narcotics including (i) a prohibition on any advertisement to the general public respecting a narcotic, and (ii) a requirement that any permitted advertisement of a narcotic must display the symbol “N” clearly and conspicuously.

The FDA and CDSA are administered by Health Canada, the national regulatory authority for drug advertisements. It provides policies to regulate drugs, puts in place guidelines for the interpretation of the Regulations, and oversees regulated drug advertising activities. There are three Canadian advertising pre-clearance agencies (“APAs”) that provide voluntary drug advertising material review services to advertisers and advertising agencies – namely, the Pharmaceutical Advertising Advisory Board (“the PAAB”), Advertising Standards Canada (“ASC”) and MIJO.

APAs use Health Canada guidance documents and, where applicable, their own codes of advertising to ensure that drug advertising materials submitted to them comply with the FDA, the CDSA, and the respective Regulations. They review advertising for consistency with the Health Canada-authorised product monograph or terms of market authorisation (“TMA”) and to verify that the advertising is accurate, balanced, evidence-based, does not expand upon or conflict with the TMA, and reflects current and best practices. In the case of the PAAB and ASC, they also offer independent complaint-resolution and appeal procedures and administer sanctions and remedial measures according to their own internal codes. During the pre-clearance review of a drug advertisement, or during the processing of a complaint or appeal, APAs may request clarification from Health Canada. Health Canada works in collaboration with APAs, but always reserves the right to enforce the drug advertising provisions contained in federal law whether or not the advertisement has been pre-cleared by an APA.

The PAAB is recognised by Health Canada as the APA for advertising material for all healthcare products directed to healthcare professionals. It is an independent multidisciplinary body that administers the PAAB Code of Advertising Acceptance (the “PAAB Code”), which was updated in 2012 and, in its new
form, will be effective on July 1, 2013 with a one-year transition period. The PAAB also provides advisory opinions on DTC messages for prescription drugs and on educational material discussing a medical condition or disease.

Like the PAAB, ASC provides advisory opinions on DTC drug advertising and DTC drug information materials. It is an independent, national, not-for-profit, advertising self-regulatory body that administers the Canadian Code of Advertising Standards (the “ASC Code”), which applies to all categories of advertising. As well, ASC has notified Health Canada that it has publicly self-attested to meeting Health Canada’s recommended criteria for the pre-clearance of DTC advertising material of OTC drugs and NHPs.

Like ASC, MIJO has notified Health Canada of its public self-attestation to meeting Health Canada’s criteria for pre-clearing DTC advertising of OTC drugs and NHPs.

Pharmaceutical manufacturer industry associations have also established self-regulation regimes. Most notably, Canada’s Research-Based Pharmaceutical Companies (“Rx&D”) has prescribed a Code of Ethical Practices (the “Rx&D Code”) for its members. Likewise, the Canadian Generic Pharmaceutical Association (“CGPA”) has had a Code of Marketing Conduct (the “CGPA Code”) governing the sale of generic pharmaceutical products in Canada (although the CGPA Code currently applies only in the provinces of Ontario and Quebec). Furthermore, the Canadian Association of Medical Publishers (“CAMP”) has Guidelines for General Advertising, Supplied Advertising Inserts, & Journal Supplements (the “CAMP Guidelines”), which apply to all advertising appearing in publications directed to healthcare professionals.

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 FDA 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.

Health Canada has issued guidelines entitled The Distinction Between Advertising and Other Activities (the “HC Ad Guidelines”) to clarify the definition of advertising under the FDA. In particular, the HC Ad Guidelines seek to clarify 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.

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” (“APSs”).

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?

The PAAB requires, in reviewing for pre-clearance a proposed advertisement to healthcare professionals, the advertiser to complete a submission form that indicates “approval” by the advertiser’s medical/regulatory/compliance department. By this “sign-off”, the advertiser confirms that the advertisement is consistent with the approved TMA and that the claims in the advertisement are supported by references that meet the standards of the PAAB Code. Neither ASC nor MIJO require such formal pre-clearance “sign-off”.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

See question 1.3 above. In a related vein, Health Canada requires ASC to implement SOPs for the pre-clearance of therapeutic comparative advertising claims, to help advertisers ensure that their claims are consistent with Health Canada requirements. There are currently three SOPs describing the steps that the ASC’s Consumer Drug Section will follow to evaluate a therapeutic comparative claim and to determine whether it is compliant with Health Canada’s Therapeutic Comparative Advertising Directive and Guidance Document: (i) Efficacy; (ii) Onset/Duration of Action; and (iii) Side Effect Profile/Safety Information.

1.5 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 may be reviewed and pre-cleared by one or more APAs in accordance with their respective mandates. For details, see question 1.1 above. Each APA is an independent entity that is expected to obtain voluntary compliance with federal drug advertising laws, and when not obtained, the matter can be returned to Health Canada, which retains ultimate authority for compliance and enforcement. Although use of these voluntary advertising pre-clearance regimes is not mandatory, it is strongly encouraged by Health Canada.

1.6 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?

The PAAB may withdraw clearance at any time and request suspension of publication if a complaint to the 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. The 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.
1.7 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 two years’ imprisonment and/or a fine of up to CAD $5,000,000. Additionally, a person who knowingly makes a false or misleading statement to the Minister of Health or who recklessly causes a serious risk of injury in contravening the Act or its regulations could face a higher fine or up to five years in jail.

The Minister of Health is responsible for enforcing the Competition Act. When Health Canada receives a complaint about a drug advertisement, it will take compliance and enforcement action as required using a risk-based approach. See question 1.8 below for more detail. 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 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, newsletters or websites, or to issue public letters of apology. Violations of the Rx&D Code will be published on the Rx&D website and subject to a fine of CAD $25,000/$50,000/$75,000 for the first/second/third violation, respectively, within a 12-month period. Upon the third violation, the Chief Executive Officer of the offending company will also be required to appear before Rx&D’s board of directors, at which time the CEO must provide a detailed explanation of the violations and a comprehensive written action plan to ensure remediation. Each additional violation after the third one results in publication of the infraction on the Rx&D website and a fine of CAD $100,000. While each unique violation of the Rx&D Code normally counts as one violation, Rx&D’s Industry Practices Review Committee (“IPRC”) has the discretion, for the purpose of setting penalties, to count any violation as two violations if the IPRC determines that such violation was a “deliberate” contravention – defined as a contravention clearly not in compliance with one or more of the Rx&D Code’s guiding principles. Compliance with sanctions is a condition of continued membership in Rx&D. Similarly, the CGPA has the power to impose penalties on advertisers who breach the CGPA Code which include a fine of CAD $15,000/$40,000/$100,000 for the first/second/third offences, respectively, within a 12-month period.

Under the general false and misleading advertising provisions of the Competition Act, a significant administrative monetary penalty (“AMP”) may be ordered for non-criminal offences. For individuals, the maximum AMP is CAD $750,000 for the first order and CAD $1 million for each subsequent order. For corporations, the maximum AMP is CAD $10 million for the first order and CAD $15 million for each subsequent order. For criminal offences (serious false and misleading representations made knowingly or recklessly, such as fraudulently promoting counterfeit cancer drugs), the maximum term of imprisonment is 14 years. A false or misleading representation is subject to action under the Competition Act even when made to the public outside Canada (e.g., through online or social media advertising), or in a non-public setting (e.g., by a sales representative). However, enforcement against drug companies on the basis of a Competition Act false and misleading advertising claim is rare given the other avenues available with specialised industry knowledge.

1.8 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?

Although APAs and self-regulatory organisations may assume pre-clearance responsibilities, Health Canada retains ultimate regulatory authority with respect to federal drug advertising laws. Moreover, Health Canada acts as an advisor to the PAAB and is an ex officio observer on the 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 APAs, their respective roles, and the adjudication of complaints and processes to submit requests for clarification are all outlined in the Health Canada’s Guidance Document – Health Canada and Advertising Pre-clearance Agencies’ Roles Related to Health Product Advertising. Annually (usually in April), Health Canada meets with APAs to discuss topical issues and common concerns in health product advertising. Each meeting’s record of discussions is posted on the PAAB’s website (usually by July).

The underlying principle behind Health Canada intervention or involvement is a perceived breach of federal drug advertising laws. With respect to the advertising pre-clearance process, Health Canada will review advertisements when they contravene federal drug advertising laws 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 in, or non-compliance with, the PAAB or ASC Codes. The PAAB and ASC are expected to refer such matters to Health Canada. Even if advertising materials are approved by the PAAB, Health Canada can ask that they be held back and not used if Health Canada is concerned that the materials pose a health threat under federal drug advertising laws.

The same principles apply to the self-regulatory complaints and appeals processes. The PAAB and ASC will bring complaints to the attention of Health Canada where, in their judgment, the complaint relates to advertising that contravenes federal drug advertising laws and presents an imminent or significant health hazard, or contravenes such laws 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.
1.9 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 Canadian law. An action for unfair competition may be brought under the common law action of passing off, or under the federal 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 healthcare professionals and patients.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare 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? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Advertisement of a drug before it has been approved for the Canadian market is prohibited by the Regulations to the FDA. The prohibition is not, however, intended to impede the free flow of information within the scientific community, including healthcare professionals. The HC Ad 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.

Under the PAAB Code, a study involving off-label use that has been completed or has been presented at a medical meeting, and includes information that is not included in the Health Canada TMA, must not be mentioned in advertising. Reference to research or ongoing studies about off-label information may be made in a non-promotional context with no prominence of information that has not been authorised by Health Canada.

Under the Rx&D Code, member companies do not support product discussion that is inconsistent with the approved prescribing information in the TMA. Promotional activities must never involve solicited discussion of unapproved or off-label uses. However, if a speaker at a scientific meeting chooses to speak about such uses of a product, they must be required by contract with that product’s manufacturer to inform the audience of this fact at the start of the presentation and a disclaimer should be written on the presentation.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information concerning unauthorised medicines and/or off-label information 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 healthcare 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 unauthorised medicines and/or off-label information? 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 healthcare professionals by the company? If so, must the healthcare professional request the information?

Information, including material concerning unauthorised products and/or off-label information, may be provided to a healthcare professional by a pharmaceutical manufacturer, only where the information has been requested by the healthcare professional. Manufacturers are prohibited from soliciting such requests.

2.5 How has the ECJ judgment in the Ludwigs case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Canada?

The ECJ judgment in the Ludwigs case has not been reflected in Canadian legislation or in practical guidance from Health Canada, any APA (such as the PAA, ASC and MJO), or any Canadian pharmaceutical industry associations (such as Rx&D and CGPA).

2.6 May information on unauthorised medicines or indications 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”.

2.7 Is it possible for companies to involve healthcare 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 the Rx&D Code, companies may involve healthcare professionals in market research exercises prior to the authorisation of medicinal products:

- market research should always be conducted for the sole purpose of collecting legitimate market information, following proper and accepted principles guiding the collection and dissemination of market research information and the treatment of the respondents and the information they provide;
- the market research questionnaire or programme should not be designed in a manner that could be interpreted to be leading to a specific response or product conclusion. It should not be used to promote the use of a company’s prescription medicines. Nor should it be used as a disguise for selling or developing sales contacts or as a substitute or disguise for clinical research;
- the number of experts consulted should be reasonable in light of the total number of healthcare professionals that are part of that specialty;
- companies should take appropriate steps to ensure healthcare professionals should not leave any market research meetings with any kind of promotional material;
- the purpose of the market research programme and, if applicable, the use of recording devices and presence of research “viewers”, must be made clear to participants at the start of the interview. The research viewers’ identities must remain anonymous to participants to preserve respondent objectivity. Viewers may not include company sales representatives, nor any other field-based personnel who have contact with and the ability to influence participants;
- even when a consent form is signed, the confidentiality and anonymity of participants and their individual responses must be preserved to the fullest extent possible. The identity of participants must not be revealed for purposes of promoting a company’s prescription medicines to them in the future. The purpose of the market research as well as the way the responses will be transmitted to the company organising the research should be transparently stated in the consent form;
- direct contact with the participants in the market research project, in which the identity of the sponsoring company is intentionally masked, should be limited to marketing research personnel only with no company sales representatives’ influence or involvement. There should be no follow-up by sales representatives or staff derived specifically from these market research projects;
- honoraria offered to healthcare professionals who gather or provide market research information should be based on industry accepted rates for market research activities and should be similar to (and not higher than) their usual rate of compensation; and
- companies must separate market research from other types of activities unrelated to the sole purpose of gathering legitimate market information.
3 Advertisements to Healthcare Professionals

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

The PAAB Code requires that all pharmaceutical advertising directed to healthcare professionals be accurate, complete and clear and designed to promote credibility and trust. Such advertisements must include at least the following:

- The prescribing information and/or link to it clearly presented within the main message;
- in juxtaposition at least once within the advertising copy, the brand or trade name of the drug, the non-proprietary (generic) name of the drug, and the federal drug schedule of the drug;
- in reflecting an attitude of caution, sufficient information in a prominent manner to permit assessment of risks and benefits of the drug; and
- the TMA content “Drug X is indicated for” (or equivalent) verbatim at least once within the advertisement.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The PAAB Code places restrictions on claims and/or quotations in advertisements. Clinical/therapeutic claims must be based on published, well controlled and/or well-designed studies with clinical and statistical significance clearly indicated. Review articles, pooled data, meta-analysis, post hoc analysis and observational studies are generally regarded as not being high-level evidence to support claims in drug advertising, but data included in the summary of product characteristics (“SmPC”) (in Canada, this is known as the “product monograph”) may be acceptable.

Non-clinical claims must be well supported by evidence. Unpublished data are regarded as having received independent review when there is evidence that the final study manuscript has been accepted by the editor of a peer-reviewed journal for future publication and when the data has been reviewed as part of a submission to Health Canada and there is evidence of acceptance indicated by inclusion in the product monograph.

Non-evidence based statements such as those from adverse drug reaction reporting systems or testimonials are not acceptable.

Claims based upon laboratory or animal testing reports should be separated and cannot be used to imply clinical significance unless there is evidence of a valid clinical correlation. Claims or quotations which are out of context or inconsistent with the conclusions of the cited author(s) are not acceptable.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The Rx&D Code prohibits an advertiser’s promotional materials from being signed by personnel who work in that advertiser’s medical, regulatory or medical/scientific information services; nor should promotional materials be signed by someone acting on their behalf, regardless of to whom they report. Signed communication from all such personnel should be limited to responses to medical/scientific information requested by the healthcare professional and essential, new medical safety information which has been requested (for example, covering letters for new product monographs and letters that advise on product safety, the withdrawal of a product, new warnings, precautions and contraindications).

Advertising or promotional campaigns that include the results of healthcare economic studies must be reviewed and approved by the PAAB following the same approval system that applies to products or services that contain clinical claims. Claims made as a result of a pharmaco-economic study or model should be consistent with the PAAB’s Guidance Document for the Use of Pharmaco-economic Studies in Advertising.

3.4 Is it a requirement that there be data from any, or a particular number of, “head to head” clinical trials before comparative claims may be 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.

3.5 What rules govern comparative 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 Related to the Therapeutic Aspects of Drugs. The PAAB Code adopts and adds to this policy, setting out various rules, which include the following:

- the compared drugs must have an authorised indication for use in common and the comparison must be related to that use or, in addition to the common indication, a second authorised indication is claimed as an added benefit of the advertised drug;
- the comparison must be drawn between drugs under the same conditions of use in a similar population;
- the claim must not conflict with the TMAs of the compared drugs;
- the claim must be of clinical relevance in humans;
- the evidence generated to substantiate the claim must be conclusive and based on (i) consideration of all relevant data, (ii) scientifically accurate, unbiased, reproducible data obtained from studies conducted and analysed using established research methodologies and validated end points, and (iii) appropriate interpretation of the data (i.e., extrapolation beyond the actual conditions of the supporting studies is not acceptable); and
- the claim and its presentation must (i) identify the compared companies (i.e., hanging comparisons such as “better” or “faster acting” are unacceptable, as are vague statements such as “compared to the leading brand”), (ii) identify the medicinal use related to the claim, (iii) not obscure the therapeutic use of the advertised drug (i.e., the comparative claim should be afforded no more prominence than the therapeutic use), (iv) not attack the compared drug in an unreasonable manner, and (v) be expressed in terms, language and graphics that can be understood by the intended audience.
Advertising that induces fear or uses scare tactics to introduce unwarranted concern will not be accepted. The PAAB Code also provides that advertising making comparative claims must acknowledge competitors’ trade-marks.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The distribution of scientific papers and proceedings of congresses to healthcare professionals may be considered a non-promotional activity where (a) the full, unedited text is made available, and (b) no link between the text and promotion of a drug is established by the drug manufacturer. Such material may be considered advertising where these conditions are not met or where other factors indicate that the primary purpose is to promote the sale of a drug, such as:

- the material is accompanied by any form of additional information designed by or on behalf of the manufacturer for the purpose of promoting a drug (e.g., a detail aid);
- the material was written or edited by an employee or agent of the manufacturer;
- a summary or interpretation of the text prepared by the manufacturer accompanies the material; or
- reference is made to the availability of an unauthorised drug through the Special Access Programme (discussed in more detail in questions 6.3 and 6.4).

### 3.7 Are “teaser” advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

The PAAB’s Guidance Document for the Submission Process (in particular, Chapter 5 entitled “Pre-NOC Advertising Submissions”) clarifies procedures for advertising review before a Notice of Compliance (“NOC”) has been granted. The chapter also confirms that under the PAAB’s mandate, it can only provide acceptances for advertising that will be disseminated after a NOC has been granted. The PAAB will not issue acceptances for any branded 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 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The Regulations to the FDA permit the distribution of product samples to registered physicians, dentists, veterinarians, surgeons or pharmacists provided that: (i) the drug is not a narcotic, a controlled drug or a drug that is not yet approved; and (ii) 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. The Rx&D Code provides further and more detailed restrictions regarding the distribution, storage, disposal and inventory of samples (also called “clinical evaluation packages”) consistent with the FDA. For example: samples must only be given to authorised healthcare professionals who, before distribution, have signed an order for samples; if no order is made when the samples are supplied, the samples must be documented on a separate “no charge” invoice; all samples must be labelled “Not for resale”; and giving out samples at convention/clinic displays, business meetings/events, or learning programmes is prohibited.

#### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

The provision of gifts or donations to healthcare professionals is governed by codes of conduct and guidelines on both the manufacturer side and the practitioner side.

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.

On the healthcare professional 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 healthcare professional committing an act of professional misconduct.

The College of Physicians and Surgeons of Ontario policy on Physicians’ Relationships with Industry prohibits physicians from accepting personal gifts of any value from industry or industry representatives. They also cannot request or accept a fee or equivalent compensation for seeing industry representatives in a promotional or similar capacity. They are, however, allowed to accept items that advance disease/treatment education, such as patient teaching aids, so long as the primary benefit of these are to the patients and the items do not have value to the physician outside of their professional responsibilities.

#### 4.3 Is it possible to give gifts or donations of money to healthcare organisations 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 giving gifts or donations of money, or donations of equipment and funding for medical or technical services, to healthcare organisations such as hospitals. However, the provision of such benefits should be made to the healthcare organisations themselves, and not to healthcare professionals employed by such organisations. Otherwise, the restrictions discussed in question 4.2 above may apply.

In addition, the Rx&D Code contains specific provisions respecting the loan of medical equipment. These include that:

- a pharmaceutical company may, through a signed written agreement clearly defining the terms of the loan, lend medical equipment to healthcare professionals in a programme at a healthcare organisation so long as the purpose of the loan is to improve the prevention, diagnosis or treatment of diseases...
in a specific therapeutic area and not to gain access to or influence such healthcare professionals or to promote specific prescription drugs;

- the written agreement must set out, among other things: (a) the programme’s objectives; (b) a detailed description of the medical equipment to be loaned; (c) the duration of the loan (which cannot be indefinite) justified by the duration of the programme; (d) that the title to the equipment must remain at all times with the pharmaceutical company; (e) that all loaned equipment must be returned at the end of the loan; and (f) that the healthcare professionals must not invoice any payer (including provincial governments, patients or insurance companies) for use of the loaned equipment; and

- the medical equipment may bear the corporate name and logo of the pharmaceutical company lender but must not bear the name of any products, or related acronyms.

Lastly, 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 healthcare professionals 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 healthcare professionals is generally allowed, provided that the goods and services do not amount to promotional efforts. Under 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 healthcare professions and the public. “Acceptable” service-oriented items are defined as those whose primary goal is to enhance the healthcare 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 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 should be cleared with the PAAB. Editorial materials that are objective, balanced and scientifically rigorous, as well as unrelated to any particular product, must still be submitted to the 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?

Provincial laws govern the permissibility of offering volume-related discounts to institutions purchasing prescription drugs. As of 2006, section 11.5(1) of the Ontario Drug Benefit Act prohibits rebates to wholesalers and pharmacies. Wholesalers and pharmacies (and their director, officers and employees) are also prohibited from accepting rebates directly or indirectly. In 2013, British Columbia followed suit and implemented “no rebate” provisions through section 21 of its Pharmaceutical Services Act. In Quebec, rebates, incentives and allowances are restricted to 15% of the total value of the sales by any given manufacturer of a generic drug (s. 22 of An Act Respecting Prescription Drug Insurance Regulation respecting benefits authorised for pharmacists).

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: (i) requires a customer as a condition of supplying product; or (ii) 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. However, the tied selling provision will only be triggered where the conduct is engaged in by a major supplier or is widespread in a market, the conduct in question constitutes a practice, the restrictive practice discourages a firm’s entry into, or expansion in, the market and the practice has substantially lessened competition, or is likely to do so. The only remedy available to the Competition Tribunal is to order the supplier to remove the contingency regarding the purchase of other medicinal products. Consequently, the scope of restrictions on this contingent purchase requirement is limited and the potential implications of non-compliance are relatively benign.

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 OTC) require that they be effective and safe. If the product is not effective or safe, it must be recalled. There are no Canadian 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 education, subject to various Rx&D Code restrictions respecting learning programmes for healthcare professionals. The restrictions draw distinctions between accredited and unaccredited continuing health education (“CHE”) programmes, as well as so-called “other learning activities” such as preceptorships (where a healthcare professional spends time with a trainer, who is a recognised expert in their field, to gain a better understanding into a therapeutic area or disease state) and speaker/faculty training workshops (where an appropriate number of healthcare professionals may be trained
Healthcare 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 healthcare 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.

The Rx&D Code contains numerous restrictions relating to hospitality provided by member companies to healthcare professionals, including:

- at a business meeting, a member company may provide reasonable meals/refreshment to healthcare professionals, but only if they are ancillary to the legitimate business activities of the meeting. No other form of stand-alone hospitality or entertainment can be provided to healthcare professionals and thus the provision of tickets and vouchers is not permitted;
- members may not hold meetings in personal residences and must avoid venues that are excessive or extravagant;
- honoraria must not be provided to healthcare professionals attending a business meeting;
- no more than five healthcare professionals may attend a business meeting where the interaction is informal. A member may invite more than five healthcare professionals to a business meeting provided the legitimate purpose of the meeting is documented through the formality of a written agenda; and
- under no circumstances can meals and refreshments be extended to the spouses/companions or administrative staff of attending healthcare professionals, even if they pay for their own meals (as the optic would not be appropriate).

The limitations on acceptable hospitality also apply to hospitality that will take place outside of Canada. In addition, the Rx&D Code provides that members must respect the applicable laws, regulations and self-regulatory codes of the country where the business meeting is being held.

Under the College of Physicians and Surgeons of Ontario policy regarding interactions with industry, physicians organising Continuing Medical Education/Continuing Professional Development (CME/CPD) activities which are industry sponsored/supported are only permitted to receive payments at fair market value, which can include reimbursements for reasonable travel, lodging and meal expenses. Physician presenters are also paid according to these guidelines. Presenters, attendees and their personal guests must pay for the full cost of any pre- or post-meeting social events.

Physician attendees to these events must not accept payment or reimbursement for travel, lodging or meal expenses from industry, but may accept meals provided at such events where they are of modest value.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

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

Similarly, provided there is an agreement in writing, the Rx&D Code allows pharmaceutical manufacturers sponsoring scientific meetings or CHE events to provide healthcare professionals who speak or moderate at such events with remuneration by way of honoraria. Any such payments must be calculated at fair market value reflective of usual rates of compensation and may only be provided after the service has been rendered. Reasonable travel, accommodation and out-of-pocket expenses, where warranted, and in line with the Rx&D Code, may be reimbursed. Remuneration and/or reimbursement of expenses of healthcare professionals merely attending the programme are prohibited.

5.2 Is it possible to pay for a healthcare professional 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?

The Rx&D Code provisions concerning learning programmes for healthcare professionals, and in particular 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 the 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 entertainment in conjunction with such an event. Hospitality arrangements are acceptable where limited to reasonable meals/refreshment, which may not be extended to the spouses/companions or administrative staff of healthcare professionals (unless they are also a healthcare professional). See question 5.1 above.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

All provincial regulatory authorities allow healthcare professionals 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.

Provided there are written agreements specifying the nature of the services to be provided and the basis for payment of those services, the Rx&D Code allows manufacturers to offer an honorarium to healthcare professionals who participate in market research. The amount of the honorarium is limited to an amount calculated based on the healthcare professional’s usual rate of pay. In addition, pharmaceutical manufacturers conducting 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 healthcare professionals. Consultant meetings (which include consulting meetings, advisory boards, and investigator meetings) must be held in Canada and may not include more than 20 individual consultants per meeting, excluding chairs, presenters and facilitators. In special circumstances, a consultant meeting may be organised by a member’s global head office and/or an international affiliate. If held outside Canada, these consultant meetings may include a maximum of 10 Canadian healthcare professionals.

The College of Physicians and Surgeons of Ontario policy on interaction with industry states that physicians who are asked by industry to participate in advisory boards or consultation boards, or to serve as individual advisors or consultants, are permitted to accept remuneration if it is at fair market value and commensurate with the services provided. Meetings must be held in the geographic locale of the physician or as part of a meeting which he/she would normally attend. Where this is not feasible, reasonable travel and accommodation expenses may be reimbursed.

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

Healthcare professionals 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 must be made pursuant to a written agreement and 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 healthcare professionals to take part in market research involving promotional materials?

Pharmaceutical companies may seek the advice and guidance of healthcare professionals 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 expense incurred in providing the consulting services. Honoraria offered to healthcare professionals 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 medicines (such as OTC drugs and NHPs) may be advertised to the general public, but such advertisements are subject to the FDA and Regulations and the Consumer Advertising Guidelines for Marketed Health Products or CAGs. The CAGs are founded on three guiding principles – namely:

- no one shall advertise a drug 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 health and safety of consumers is paramount; and
- advertising should clearly communicate the intended use of the product in a manner that is consistent with the TMA in order to allow consumers to make an appropriate and informed choice.

With respect to “product characteristics”, the CAGs establish the following 10 guidelines accompanied by specific applications and examples:

- Authorisation – therapeutic claims must be consistent with the TMA of the product;
- Product Representation – an advertisement must not be misleading as to the product category under which it received its TMA, or misrepresent its therapeutic properties;
- Indication – Single Medicinal Ingredient – the advertisement must clearly communicate the intended therapeutic use of the product as per its TMA;
- Indication – Multiple Medicinal Ingredients – the advertisement must clearly communicate the symptoms that the product is intended to treat/relieve, or the intended therapeutic use as per the product’s TMA;
- Directions – an advertisement must not be misleading as to the directions for use/dosage and administration;
- Duration of Action – an advertisement must not be misleading as to the duration of action of the product;
Duration of Use – an advertisement must not be misleading as to the duration of use of the product;

Efficacy – an advertisement must not be misleading by directly or indirectly exaggerating the degree of relief/benefit to be obtained from use of the product;

Medicinal vs. Non-medicinal Ingredients – product benefits must not be presented in a manner that misleads the consumer as to the nature of either the medicinal (therapeutic) or non-medicinal (non-therapeutic) ingredients; and

Onset of Action – an advertisement must not be misleading as to the time to onset of action of the product.

With respect to “product claims and representations”, the CAGs establish 32 guidelines accompanied by specific applications and examples, some of which, by way of example, include the following:

Clinically Tested/Proven – an advertisement must not be misleading with respect to the statement “clinically tested/ proven”;

Endorsements/Seals – endorsements and seals must not be used in a manner that creates an erroneous impression regarding product merit;

Extra Strength/Maximum Strength – an advertisement must not be misleading by suggesting that an “extra” strength product provides a greater benefit than a “regular” strength product where both are indicated for the same condition;

Health Canada Approved – an advertisement must not make any reference to the FDA or its Regulations unless such reference is a legislatively prescribed requirement. For many years, in application of this guideline, Health Canada has taken the position that the advertisement cannot state or imply product authorisation by Health Canada (although it is acceptable to include the actual Drug Identification Number (“DIN”), Homeopathic Medicine Number (“DIN-HM”) or Natural Product Number (“NPN”) in an advertisement). That said, Health Canada has recently indicated that it will now permit the claim “Product A is authorised for sale by Health Canada” in the advertising of an authorised healthcare product bearing a DIN, DIN-HM or NPN. This change appears to be in response to requests from healthcare product manufacturers to be able to more clearly communicate to Canadian consumers the distinction between their authorised healthcare products and unauthorised third party products. It is anticipated that Health Canada will include this change in the next version of the CAGs which are presently in revision;

Healthy – an advertisement must not be misleading by suggesting that a product may restore, maintain or promote health, unless such claims are included in the product’s TMA;

Natural – an advertisement must not mislead a consumer to believe that a non-prescription drug or a NHP is “natural”, if it is synthetically derived;

New/Improved – the terms “new” and “improved” may be used for a period of one year from the date of marketing a new formulation;

Risk/Safety Information Communication – in order to make informed decisions about their health, consumers should be provided with fair and balanced information about the benefits and the risks associated with the use of the product;

Safe/Side Effect Free – claims stating “safe”, “side effect free” and “no known side effects” are unacceptable;

Scare Advertising – an advertisement must not create an erroneous impression regarding the merit of a product through use of fear-inducing copy or visuals;

Supers – superscripts and footnotes (also known as “supers”) should not be used to correct an otherwise misleading impression about a product; and

Therapeutic Guarantees/Absolute Claims – an advertisement must not be misleading as to the merits of a product by directly or indirectly suggesting that it will be effective for all individuals, or that it will be effective every single time it is used.

The CAGs form the basis upon which APAs review and approve advertising for non-prescription medicines and thus help ensure consistency in advertising review. Both ASC and MJO provide a review and pre-clearance service for DTC advertising of OTC drugs and NHPs.

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 FDA. No person shall advertise a new prescription drug unless the Minister has issued a NOC to the manufacturer of the new drug. The law prohibits any DTC advertising of narcotic drugs and controlled drugs. Prescription Drug List 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 FDA prohibits any advertising to the general public of prescription drugs as a means to prevent, treat or cure conditions listed in Schedule A of the FDA (see question 1.1 above). Schedule D vaccines that would require a prescription for sale in Canada may be advertised subject to satisfying the “fair balance” requirement as described in Health Canada’s Interim Guidance – Fair Balance in Direct-to-Consumer Advertising of Vaccines – namely, the advertising must present accurate, truthful, objective and balanced information on the benefits and risks of the vaccine. The FDA also prohibits the distribution of a drug as a sample, except in the case of distribution to designated healthcare professionals (such as doctors and pharmacists). Finally, the FDA 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 advertisers are required to limit their advertising of prescription drugs 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 (often called “help seeking” ads). Such informational 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 the context and content of an advertising campaign will be considered as a whole. Thus, advertisers must be careful not to reveal their sponsorship of the “help seeking” ad, directly or by including similar themes, characters or other identifiable aspects which link the “help seeking” ad with a “reminder” 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 FDA 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 these messages cannot be linked to a specific product, and the “help seeking” ad with a “reminder” ad. Thus, advertisers must be careful not to reveal their sponsorship of the “help seeking” ad, directly or by including similar themes, characters or other identifiable aspects which link the “help seeking” ad with a “reminder” ad.

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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 (“SAP”). 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.

Biologics (such as vaccines) and radiopharmaceutical drugs listed in Schedules C and D of the FDA, respectively, are not subject to the same stringent DTC advertising restrictions as prescription 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 HC Ad 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 SAP. The SAP allows physicians to request access to drugs that are unavailable for sale in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.

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 FDA, 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.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

The Rx&D Code provides that its members must ensure that the funding of patient organisations, such as patient 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. See also question 5.7 above.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Health Canada regulates new drug submissions, and in doing so requires the results of clinical trials before approving new drugs for use or sale. Under Division 5 of the FDRs, companies must submit an application to Health Canada for authorisation to sell or import a drug for the purpose of a clinical trial. Sponsors must then file applications to conduct clinical trials in Phases I through III of drug development. Companies must disclose the results of their clinical trials to Health Canada in their new drug submissions. During the clinical trial, sponsors also have an obligation to report any serious unexpected adverse drug reactions. Health Canada reviews and evaluates the clinical trial results when determining whether to approve the drug for use or sale.

Additionally, the Rx&D Code contains detailed provisions relating to “post registration clinical studies”, defined as any study within the approved indications that is conducted after Health Canada’s NOC has been issued for a prescription drug. The provisions include:

- the underlying purpose of the study cannot be to familiarise healthcare professionals or patients with the use of the prescription drug or to encourage its prescription (in other words, so-called “seeding” or “experience” trials are not acceptable);

- the main purpose of the study must be to answer scientific questions which require obtaining and evaluating data on safety, efficacy, effectiveness, cost effectiveness, quality of life, functional and other socio-economic factors that have to do with the clinical use of the prescription drug; and
7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

Unlike the US, which imposes disclosure obligations on pharmaceutical companies through the Physician Payment Sunshine Act (to encourage greater transparency regarding transfers of value between such companies and physicians and hospitals), Canada has yet to enact similar legislative requirements.

The Rx&D’s Guidelines for Transparency in Stakeholder Funding describes the standards member companies are expected to meet when involved with stakeholder (i.e., patient groups, health charities, professional associations, academics or the business community) funding. The Guidelines require members to regularly disclose, by means of their websites and annual reports, a list of all stakeholders to which they provide direct funding. They are also expected to post their commitment to engage in transparent funding practices with stakeholders.

The level of detail need not be particularly high for disclosure of direct funding. As an example, if a member company provided a number of grants to various patient groups, it may simply post wording such as “We are proud to support the following organisations and groups in 2008 (followed by a list)” on its website.

Furthermore, the Rx&D Code of Ethical Practices generally encourages disclosure of any resources (including financial or in kind) provided by a member company for planning, implementing and administering a learning programme for healthcare professionals, or sponsorship of congresses, symposia, conventions and other similar events.

8 The Internet

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

The advertising of drugs in Canada on the internet is regulated in essentially the same way as traditional advertising. Both are subject to the many laws, regulations, guidelines and codes already described above. There are, however, several internet-specific guidelines and codes as described below.

Of general application to all Canadian advertising, the federal Competition Bureau’s Information Bulletin, entitled Application of the Competition Act to Representations on the Internet, provides guidance to advertising online. Also, various internet-specific industry standards have been adopted and continue to evolve as the need for clarification arises. One such standard is the Digital Marketing Guidelines of the Canadian Marketing Association.

While strictly speaking not binding on Canadian courts and regulators, the US Federal Trade Commission’s published.com Disclosures: How to Make Effective Disclosures in Digital Advertising gives sensible guidance and practical examples on how to make clear and conspicuous disclosures in internet advertising – especially when that advertising is accessed on social media platforms or on mobile devices with space-constrained screens.

The provisions respecting commercial electronic messages (“CEMs”), which includes emails, texts and social media messages, in Canada’s anti-spam legislation (“CASL”) came into force on July 1, 2014. CASL requires express opt-in consent to receive CEMs. There are only limited exceptions to this otherwise stringent requirement. However, consent may be implied where an existing business relationship exists with the recipient, or the CEMs are relevant to the recipient’s business, role, function or duties, and the electronic address has been conspicuously published or disclosed, without a statement that the recipient does not wish to receive unsolicited CEMs. CASL also requires certain content in CEMs, including prescribed information identifying the CEM sender and an unsubscribe mechanism. Under CASL, the offences are broad and the consequences of violations are severe. These consequences include a maximum CAD $10 million AMP for a corporation’s first violation and, as of July 1, 2017, liability for damages arising from a private right of action by recipients (either individually or as a class) of a CEM sent in contravention of CASL. Accordingly, advertisers and their representatives that communicate to healthcare professionals, patients and consumers in Canada via e-mail, texts, messages on social media platforms, mobile devices and other electronic means now have to ensure that their practices comply with CASL.

CASL also amended, effective July 1, 2014, the “deceptive advertising” provisions of the federal Competition Act to include a new civil reviewable practice and a new criminal offence in connection with electronic messages. Neither provision contains the usual “materiality” requirement that has always been a key element of the Competition Act’s general deceptive advertising provisions. On the civil side, the sender of an electronic message cannot make a deceptive representation in (i) either the sender information or subject matter information of an electronic message, or (ii) in the locator – i.e., the name or other information used to identify the source of data in a computer system (like a URL). If the sender contravenes this prohibition, the maximum penalty for businesses is a CAD $10 million AMP for the first contravention and a CAD $15 million AMP for each subsequent contravention. On the criminal side, the sender cannot “knowingly or recklessly” make a deceptive representation in the sender information, subject matter information, or the locator of an electronic message. If the sender commits this offence, they are liable on indictment to a fine at the discretion of the court (i.e., no maximum) and/or up to 14 years in jail (with no conditional sentence); on summary conviction, the consequences are a fine of up to CAD $200,000 and/or up to one year in jail.

Lastly, CASL contains provisions that came into force on January 15, 2015 regarding the installation of computer programs on someone else’s computer – namely, a person must not, in the course of a commercial activity, install a computer program on another person’s computer without their consent. Consent must be express, not implied. But there are some deemed consent provisions. CASL’s “computer program” rules may, for example, apply to mobile apps dealing with disease/condition/medication management, product use and patient programmes, to name a few. Failure to comply with these requirements subjects pharmaceutical companies to the same legal risks as those for contravening CASL’s “anti-spam” rules discussed above.
With respect to drug advertising specifically, the PAAB Code has long provided some guidance for acceptable advertising on the internet. Reflecting the increased use of the internet and social media platforms to advertise to healthcare professionals, this guidance has been expanded and made more specific in the revised PAAB Code and in a 22-page companion guideline entitled Guidance Document for Online Activities that the PAAB published in January 2013. The key guidelines include:

- the name of the pharmaceutical company that sponsors any online media platform should be stated on every page of the website controlled by the sponsor, unless use of the company name is prohibited by regulatory requirements or third party owners;
- the sponsors of websites that allow user-generated content (“UGC”) must monitor these pages, provide terms and conditions to users who engage in commentary, and describe the types of comments that will be modified or removed from the site. That is because the presence of UGC on a sponsored website can render a compliant page non-compliant by the comments that have been made. Misinformation must be corrected or removed. Off-label discussions must also be removed. That said, with respect to the internet generally, no pharmaceutical company is required to perform screening, monitoring or listening activities as the PAAB recognises that monitoring the entire internet for information is impossible;
- in place of prescribing information, the advertiser may provide either a URL or a direct link to the product’s TMA;
- the linked webpage need not be reviewed by the PAAB if no additional advertising content, apart from a corporate logo and tagline, is displayed on the page. If, however, there is additional advertising content, then the PAAB must review the linked page;
- banner ads, pop-up ads or microblogs that contain either direct or implied product claims must include risk/benefit fair balance and be page-linked to the TMA;
- for physician, patient or consumer access to industry-sponsored websites, platforms or networks, the sponsor should provide adequate and sufficient mechanisms (such as user authentication and gating barriers) to determine the regulatory category of the person requesting the information online;
- for sites containing content relating to prescription drugs and/or healthcare products promoting the treatment or cure of Schedule A diseases, the mechanism must pose a true barrier restricting consumers from having access to the site;
- for sites directed at healthcare professionals, the gating mechanism may be their provincial licence number or a password distributed in a controlled manner by the manufacturer;
- for sites directed at patients, sponsors should provide control of distribution of the password allowing entry to the sponsored location. The Drug Identification Number or DIN is an acceptable password; and
- sponsors should not provide the text of a meta-data descriptor that contains direct or implied product claims to a search engine that would contravene any federal regulatory requirements for drug advertising. Any descriptor under the control of the sponsor, for patient and/or healthcare professional sites must be submitted to the PAAB for pre-clearance review. Keywords and other meta-data tags that refer to competitor products are prohibited because it is deemed unethical.

### 8.2 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 healthcare professionals?

The PAAB Code and Guidance Document for Online Activities provides that information or advertising on a website that is directed at healthcare professionals should be identified as such. The following suggestions are provided:

- use authentication measures and gating barriers such as 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 healthcare professionals as opposed to the general public.

### 8.3 What rules apply to the content of independent websites that may be accessed by a 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 Prescription Drug List drug. The FDA and Regulations, the Competition Act, the Rx&D Code and the PAAB Code apply to pharmaceutical product advertising intended for healthcare professionals and placed on internet websites that originate in Canada and are controlled by Canadian pharmaceutical companies. Third-party links to websites where entry is in close proximity to content that contravenes the PAAB Code are prohibited. A message should appear telling the viewer when they are leaving the sponsor’s website. Promotion of a website that contains promotional information by non-web-based mechanisms would require prior PAAB pre-clearance review of the website content. 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 Competition Act to Representations on the Internet, the Competition Bureau will focus on the party that 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: (i) does not have decision-making authority or control over the content; (ii) accepted the representation in good faith and in the ordinary course of business; and (iii) recorded the Canadian-based advertiser’s name and address.

### 8.4 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 to the requirements of federal drug advertising laws. Companies may not promote the sale to the public of a prescription drug except for name, price and quantity or advertise a drug as a
proposals to amend the FDA. Bill C-51 died on the Order Paper when Parliament was dissolved for a federal election in Fall 2008. The Government of Canada has since communicated that it remains committed to moving forward with modernising the legislation. In 2010 and 2011, a series of technical discussions with stakeholders respecting this modernisation were held. The technical discussion document on “advertising” that Health Canada prepared and circulated in advance of the discussions proposed a model that limits the advertising of prescription drugs to the general public only when Health Canada is of the opinion that a significant public health need could be addressed by such advertising (e.g., advertising for certain vaccines under some circumstances).

On July 31, 2012, a summary of feedback received from these discussions was posted on Health Canada’s website. With respect to “advertising”, this summary includes the following points:

- there was strong support by all participants (other than from industry) to eliminate all forms of DTC advertising for prescription drugs;
- it was suggested that rules banning DTC advertising be incorporated in legislation to remove any possibility of changes being made through regulation; and
- it was acknowledged that the ease of access to information on the internet and in the social media age has to be considered.

Of course, with 2015 being a federal election year in Canada, it remains to be seen whether, and if so when, any of these points make their way into Health Canada proposals for legislative and/or regulatory change and, following publication in the Canada Gazette and public consultation, ultimately new laws. From the publicly available record of discussions between Canadian APAs and Health Canada, it seems that Health Canada is working on developing regulatory proposals and will continue with stakeholder consultations going forward. One key policy document, especially pertinent to drug advertising, that Health Canada is working on updating is its Distinction Between Advertising and Other Activities (last updated in 2005).

There are two trends that suggest Canada’s voluntary pre-clearance system may be working well. First, the number of complaints about drug advertising has dropped over the past couple of years. And secondly, over the same period, the volume of pre-clearance reviews has increased.

At the same time, however, Health Canada has seen an increase in complaints regarding the advertising of medical devices and accordingly is in discussion with APAs to consider the establishment of a voluntary pre-clearance system for such products akin to the one in place for drugs. Health Canada may also be updating the Consumer Advertising Guidelines for Marketed Health Products: Non-prescription Drugs including Natural Health Products to include advertising of medical devices (along with vaccines).

In addition, Health Canada has seen an increase in complaints particularly in regard to the advertising of NHPs and OTC drugs, which has resulted in an increased use of ASC as an adjudicator to resolve consumer complaints related to the advertising of such products. Lastly, off-label representations (especially in the context of UGC and internet advertising) and compliance of advertising in mobile phone applications (“apps”) seem to be enforcement concerns of Health Canada and APAs (as evidenced, in part, by the extensive treatment of online advertising under the revised PAAB Code).
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Bill is a longstanding member of the Canadian Marketing Association’s Ethics & Privacy Committee and the American Bar Association Anti-trust Section’s Consumer Protection Committee. He is recognised as a leading lawyer in Advertising & Marketing by The Canadian Lexpert Legal Directory and The Best Lawyers in Canada.

Bill is a frequent presenter in the life sciences area (most recently, the Canadian Institute’s Drug and Medical Device Liability and Litigation in Canada) and has authored numerous publications, including the 2013 edition of this chapter, the “Misleading Advertising and Marketing Practices” chapter in Fundamentals of Canadian Competition Law (2015) and the “Canada” chapter in the Getting the Deal Through international and comparative Advertising & Marketing Law Guide, 2015. He is also a major contributor to DLA Piper’s CASL Resource Centre, a free online source of information on complying with Canada’s tough and relatively new anti-spam laws. Bill was called to the Ontario Bar in 1988, has an LL.M. from the University of Cambridge, an LL.B., and a B.A. from the University of Toronto.

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On April 17, 2015, Davis LLP combined with DLA Piper LLP and adopted the name DLA Piper (Canada) LLP. The combination unites the breadth of practices and industry experience of DLA Piper, one of the world’s leading global law firms, with Davis, a firm with deep roots in the Canadian and international business communities.

DLA Piper (Canada) LLP’s life sciences team is part of a global team across more than 30 jurisdictions. We combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our pharmaceutical, medical device and diagnostics clients.

Recognising that our clients’ needs vary, we rapidly organise and customise our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter, whether it is an international deal, investigation/litigation or cross-border advisory project.