PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The federal Food and Drugs Act (FDA), the Food and Drugs Regulation (FDR), and the Medical Devices Regulations (MDR) largely regulate the advertising of pharmaceutical products and medical devices in Canada. Health Canada, which enforces these regulatory instruments, publishes supplementary guidance documents to assist industry stakeholders understand their obligations under this legislation. The federal Competition Act also applies to deceptive marketing practices.

Industry groups working in collaboration with Health Canada have also developed generally accepted codes of conduct for advertising pharmaceuticals to the general public and healthcare professionals (HCPs). The Pharmaceutical Advertisement Advisory Board's Code of Advertising Acceptance[1] (the 'PAAB Code') and Advertisement Standards Canada's Canadian Code of Advertising Standards[2] (the 'ACS Code') are the two most pertinent industry codes aimed at governing pharmaceutical advertising. In addition, Innovative Medicines Canada (IMC) is a voluntary membership-based industry association that maintains its Code of Ethical Practices (the 'IMC Code'),[3] compliance with which is mandatory for its members. Many prominent pharmaceutical companies in Canada are IMC members.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

The FDA defines 'advertising' as 'any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device'.[4] This definition is applicable to both pharmaceuticals and medical devices. While promotional messages are considered advertising, non-promotional representations are not subject to advertising restrictions in the FDA.

Health Canada has published extensive guidance on the distinction between promotional and non-promotional representations.[5] Health Canada evaluates each representation in its entirety, including any accompanying links to other materials, messages, or websites. The fundamental distinction between promotional and non-promotional representations is the representation's primary purpose. Health Canada may look to several factors in making that determination, including the context in which the representation was disseminated and by whom, whether the representation is sponsored and by whom, and the identities of the primary and secondary audiences.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

Health Canada is the regulatory authority responsible for regulating and enforcing the FDA and its regulations, which set out the primary legal restrictions on pharmaceutical and medical device advertising. The Competition Bureau is the regulatory authority that enforces the Competition Act, which contains general prohibitions against deceptive marketing practices and anti-competitive behaviour.

Health Canada has also delegated authority to, and works in collaboration with, two advertising preclearance agencies (APAs):

- Advertising Standards Canada (Ad Standards) which acts as an APA for advertisements directed to the general public; and
- the Pharmaceutical Advertising Advisory Board, an industry-based self-regulatory body and an APA for advertisements directed to HCPs.

APAs do not have legal authority to stop the publication of offending advertisements or issue fines or other penalties. If an APA detects or receives a complaint of a non-compliant advertising, it may then forward a complaint to Health Canada or the Competition Bureau. Health Canada and the Competition Bureau are likely to priortise complaints from APAs given their role in self-regulating the pharmaceutical and medical industries.

Two prominent industry organisations that have developed their own codes of conduct setting compliance standards for their memberships (which are voluntary) are:

- IMC, which maintains its Code of Ethical practices; and
- the Canadian Generic Pharmaceutical Association (CGPA), which maintains its Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

The FDA general advertising restrictions apply to food and a range of health products, including prescription and non-prescription drugs, medical devices, natural health products, and animal health products (eg, veterinary drugs and veterinary health products). Further information regarding these specific requirements can be found in the FDA, the FDR (for food and drugs), the Medical Device Regulations SOR/98-282 (MDR), and the Natural Health Products Regulations SOR/2003-196. For example, the MDR prohibits any person from advertising a Class II, III, or IV medical device unless the medical device's manufacturer holds a Medical Device Licence issued by Health Canada.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

Both pharmaceuticals and medical devices are subject to a general prohibition against false, misleading, or deceptive advertising. With some exceptions, only persons with the appropriate licensing may advertise a pharmaceutical or medical device for sale.

Prescription drug advertisements directed to the general public are subject to significant restrictions under the FDA and the Controlled Drugs and Substances Act. The content of these advertisements must not make any representations beyond the name, price, and quantity of the drug, and must not discuss a specific disease state or symptoms. Prescription drug advertisements to HCPs are less restricted and may contain more information than merely a drug's name, quantity, and price.

Regardless of the audience, no person may advertise a drug or medical device as a treatment, preventative, or cure for certain diseases listed in Schedule A.1. to the FDA (eg, asthma, cancer, depression, diabetes, etc).

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The laws and codes of practice regulating pharmaceutical and medical device promotion/advertising apply to all forms of advertisement, regardless of the medium. Internet and social media advertisements may be subject to scrutiny by Health Canada if user-generated content (including comments) is contrary to the restrictions under the FDA and FDR. Ad Standards recommends that advertisers consider locking these webpages, limit user-generated content to votes, quizzes, or other limited response mechanisms, and monitor and remove non-compliant content like impermissible testimonials.

Online advertisements are also subject to Canadian federal anti-spam legislation. Anti-spam legislation requires that users consent to the receipt of commercial electronic messages. Such commercial electronic messages are also subject to prescribed requirements, such as the mandatory inclusion of an 'unsubscribe' mechanism.

Finally, companies that advertise drugs to HCPs may wish to use so-called 'gating mechanisms' to prevent the general public from accessing advertisements that contain any representations beyond the name, price, and quantity of the drug. The PAAB's 'Gating Mechanisms for HCP Digital Assets'[6] contains further information on gating mechanisms.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Health Canada generally encourages, but does not mandate, the use of an APA. Health Canada can, however, mandate in a drug's Terms of Marketing Authorisation that an APA preclear the drug's

advertisements. Health Canada acts as an ex officio observer and advisor to certain APAs, without relinquishing any part of its authority under the FDA and its associated regulations.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Advertisement of unauthorised pharmaceuticals and/or off-label information (ie, unauthorised indications) is not permitted. Educational/non-promotional dissemination of information regarding unauthorised pharmaceuticals and/or indications is permitted, provided these activities do not occur in a context that may render them 'advertising' in the eyes of Health Canada. Health Canada's 'Guidance on distinction between advertising and other activities for health products'[7] outlines two context factors that may render an informational/educational message advertising:

- the message does not caution that the drug's safety and effectiveness are still under investigation and the drug has not yet received market authorisation in Canada;
- the message suggests the drug is available through Health Canada's Special Access program. The Special Access Program provides opportunities for HCPs to obtain drugs for patients for whom conventional treatments have failed, are unsuitable, or are not available in Canada.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

All comparative therapeutic claims must follow Health Canada's Therapeutic Comparative Advertising Directive.[8] A comparative claim is a statement that 'compares an identified attribute of one drug product/ingredient to that of another/other drug product(s)/ingredient(s) in terms of comparability or superiority'.[9] Comparative claims must be based on sound scientific evidence and therapeutic aspects in the drug's Product Monograph.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

HCPs are defined differently between each of Canada's provinces and territories. Most provinces have both a general statute covering all HCPs, as well as many individual statutes, setting out the regulatory regime of each HCP. In Ontario, for example, the Regulated Health Professions Act 1991[10] sets out the general rules applicable to health professionals. The Medicine Act 1991,[11] sets out the specific limits and obligations related to physicians.

Further, the PAAB Code discusses promotional communications regarding health product information that are directed to HCPs. The PAAB Code requires amongst other things, for example, that pharmaceutical advertising directed at HCPs include: the brand or trade name of the drug; the non-proprietary (generic) name of the drug; and the federal drug schedule of the drug (if a prescription product).

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no rules specifically governing promotional activity conducted virtually, and the same rules apply as they would to in-person interactions. Health Canada guidance, however, notes information disseminated through social media and other electronic interactive tools may constitute 'promotional material' where:

- the website, platform, or other technology is branded;
- links or other interactive features connect users to material that emphasises a specific product and its benefits;
- the sharing options could modify the context by which the content is disseminated to reach different audiences or emphasise a specific product;
- the sponsor engages in discussions beyond monitoring the social media activity; or direct or indirect therapeutic or safety comparative claims are made.[12]

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

There are provincial statutory restrictions on HCPs providing endorsements for advertising materials. For example, the Ontario Regulations 114/94 governing physicians preclude any member of the College of Physicians and Surgeons of Ontario (CPSO) from communicating with reference to a specific drug, appliance, or equipment (sections 6–8). Physicians may not make statements containing testimonials, comparative, or superlative statements (section 6(2)(b). There are also ethical hurdles to obtaining such endorsements, including specific limits on the sale and promotion of medical supplies and devices by physicians, as well as their relationships with industry.[13]

Further, Ad Standards' 'Guidelines for Consumer Advertising of Health Products for Nonprescription Drugs, Natural Health Products, Vaccines, and Medical Devices' (the 'Ad Standard Guidelines') provide restrictions on the inclusion of endorsements in advertisements for health products. While testimonials, quotations, and endorsements are permitted, the claims made in the endorsements must accord with the terms of market authorisation.[14] Where a claim is made that a product is endorsed by an organisation, or bears the seal of a recognised group, the advertiser should possess, and be prepared to produce, evidence to this effect.[15] Moreover, it is the responsibility of the advertiser to ensure that content generated on its website by users (comments) is consistent with the drug's terms of market authorisation.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The FDR and IMC Code provide regulations and guidance related to samples of drugs. The FDR allows for distribution of drug samples to registered HCPs, subject to the following limitations:

- The HCP must sign an order specifying the proper name or common name, the brand name and the quantity of the drug (this requirement is excepted for certain classes of non-prescription drugs).
- Samples cannot be provided for a narcotic as defined in the Narcotic Control Regulations, a controlled drug as defined in the FDR; or a prescription drug as defined in the Cannabis Regulations.
- Samples may only be provided to HCPs that are entitled to prescribe or dispense that drug under the laws of the province in which they are practising.[16]

The HCP may then dispense the therapy free of charge, for patient treatment.[17] Restrictions and requirements are in place for the storage, disposal, inventory, and distribution of samples. Distributing samples at conventions, clinic displays, meetings, or learning programs, is prohibited.[18]

But for a few exceptions, there are no regulations specific to the provision of medical devices on a sample or trial basis. MedTech Canada Code of Conduct (at page 8) provides guidance as to the conduct of parties in the context of providing samples of medical devices for a limited trial period to HCPs, free of charge.

Distributing gifts, whether in cash or otherwise, to HCPs as an incentive or reward for the administration, recommendation, approval, or otherwise of a product is not permitted.[19] 'Service-oriented items', whose primary goals are to enhance the HCPs' understanding of a condition or treatment, are permissible.[20] These items may bear the corporate logo and name, but must not bear any product name.[21] Examples include patient agendas, patient calendars, and textbooks (of reasonable value), but *not* office supplies, bags, stress balls, or publication subscriptions.[22]

14. What rules govern the offering of hospitality to healthcare professionals?

Though industry organisations may offer hospitality to HCPs, the HCP may be prevented by the conflict of interest regulations and policies from accepting such hospitality. For example, the CPSO policy on relationships with industry provides that physicians must not accept payment or reimbursement for travel, lodging, or meal expenses, other than meals of a 'modest value' at the event itself.[23] Speakers and presenters may accept payment which is commensurate with services provided and at 'fair market value'.[24] Speakers, panelists, and organisers must disclose any financial support they receive from industry.[25]

The IMC and CGPA Codes provide insight into the expectations for industry organisations. The IMC code mirrors the CPSO requirements: renumeration of a speaker or moderator must be an honorarium at fair market value,[26] and reasonable travel, accommodation, and out-of-pocket expenses may be reimbursed.[27] The IMC Code dictates that industry members cannot pay for registration fees or travel expenses for learning

program attendees,[28] or their spouses, companions, and family members.[29] By contrast, the CGPA Code allows members to pay reasonable expenses for conference attendees.[30]

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

There are no specific regulations or policies on donations to healthcare institutions or organisations, but Health Canada's guidance on promotional activities dictates that any activity is considered on a case-by-case basis, and may be considered promotional.[31] As such, whether a donation constitutes a promotional tool will be context-specific.[32]

Guidance may be taken from industry groups. The IMC Code provides that donations may be made to support healthcare, including charitable and philanthropic organisations.[33] The industry member is not to control or influence the activity being funded.[34] Donations must not be provided to private medical practices or clinics.[35] As well, MedTech Canada Code of Conduct (see page 6) also provides useful guidance related to grants and charitable donations that may be made to certain health care organisations and HCPs under certain conditions.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Health Canada's guidance provides that financial support for learning activities may be promotional in nature, especially where the financial support is not disclosed (for instance, by a speaker) or where there is not sufficient editorial independence over the content of the educational materials.[36] HCPs are also obligated to disclose such support and partnerships under their own professional regulations and ethical guidelines, or to avoid them altogether.[37]

The IMC Code indicates that pharmaceutical companies may support both accredited and unaccredited educational programs delivered by and for HCPs.[38] The topics of sponsored educational events must not be 'promotional-oriented', and must give a balanced view of the available therapeutic options.[39] Editorial control of presentation content must rest solely with the healthcare providers.[40] Under the IMC Code, industry may not sponsor congresses held outside of Canada.[41] Where industry sponsors scientific and educational meetings, the IMC Code supports the disclosure of any financial or material affiliation with industry.[42]

There are no industry-specific regulations or policies for medical device manufacturers supporting scientific and education meetings. Health Canada's guidance, and the professional obligations of attendees, will still apply to such support.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

Health Canada guidance notes that industry support of patients' groups may be considered promotional in some instances, for example: where the group does not make the role of industry clear to members, where events are product-focused, and where treatment options are not discussed objectively.[43]

The IMC Code contains provisions concerning the funding of patient support programs. Where members support such programs, they must not duplicate, replace, or compete with services and resources provided by the existing healthcare system.[44] They must also not serve as an incentive to gain access to a medical practice, inducement to prescribe a medication, or in a manner that could be construed as a gift.[45]

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

There are no specific rules, regulations, or guidance, on third-party advertising through service agreements or co-promotion arrangements. However, the federal and provincial framework governing promotion and advertising of pharmaceuticals and medical devices in Canada applies to such activities and therefore, each case must be carefully considered to avoid non-compliance and potential enforcement action.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

There are currently no mandatory federal requirements to report such transfers. However, in Ontario, the proposed Health Sector Payment Transparency Act will introduce reporting requirements for all individuals who receive transfers of value from drug or medical product sellers, manufacturers, or marketing firms.[46]

This Act is not yet in force and no date to be in force is proposed. HCPs may be under obligations to disclose transfers of value to the relevant regulatory body, under relevant conflict of interest policies.[47]

Further, the IMC Code at Annex A provides an annex regarding transparency in transfers of value and stakeholder funding for voluntary disclosure. It notes that industry members must regularly disclose stakeholders to whom they provide funding. Further, it encourages industry members to make clear that there is mutual understanding between the industry and the recipient of funds as to the parameters of funding.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Health Canada's Health Product and Food Branch Inspectorate has a range of measures available should a breach be considered serious. These include fines, injunctions, prosecution and imprisonment, forfeiture, public warning or advisory, letters to trade and regulated parties, regulatory stop sale, search and seizure, seizure and detention, suspension or cancellation of marketing authorisation/product licences or establishment licences, or warning letters.

Individual regulatory colleges may take action against an HCP where the HCP violates provincial laws or professional standards. If and when regulatory colleges take action, the ramifications for HCPs may include warnings, suspensions, fines, or the revocation of their licence. Regulators across the country have different approaches to publicising decisions, with most publishing disciplinary decisions publicly.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

See Question 22 below.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Canadian pharmaceutical and medical device stakeholders welcomed Health Canada's much awaited guidance on the distinction between advertising and other activities for health products in July 2023. The guidance document applies to prescription drugs (including controlled substances), non-prescription drugs, vaccines, biologics, medical devices, natural health products, and animal health products. The guidance replaces previous issued guidance by the regulator (including a draft guidance for the sector of 2019). Health Canada has yet to release its 2024–2025 Departmental Plan, however we expect over 2024, Health Canada to continue to work closely with industry, public health authorities, and international regulators to monitor the safety and effectiveness of authorised health products and to rapidly investigate and mitigate risks, including taking steps to protect Canadians from false and misleading advertising.

Of note, Health Canada's enforcement action of non-compliant advertising has generally not attracted significant enforcement action. For example, since 2014, the regulator has dealt with over 1,273 complaints[48] against a multitude of companies in Canada where much of the focus has been on advertising unauthorised products and direct-to-consumer advertising of authorised and unauthorised products. A review, however, of the regulator's action taken on each such incident shows that the complaints were resolved largely through a correction of non-compliance and without escalation to imposing sanctions, penalties, and prosecution for such non-compliance.

We also note recent amendments to the Competition Act make it such that private parties – such as competitors – can seek leave from the Competition Tribunal to combat prohibited pharmaceutical advertising. The Competition Act contains analogous legislation to section 9 of the FDA that prohibits deceptive and misleading advertising.[49] Similar to section 9 of the FDA, section 74.01 provides that advertising can be 'misleading' if it is 'misleading in a material respect' or if it makes claims related to the 'performance, efficacy or length of life of a product that is not based on an adequate and proper test thereof, the proof of which lies on the' advertiser.[50] The Tribunal will only grant leave if the Tribunal is satisfied that it is in the public interest to do so, which creates a high threshold to challenge advertising.

Notes

1 Pharmaceutical Advertising Advisory Board available at: code.paab.ca.

2 Ad Standards available at: adstandards.ca/code/the-code-online.

3 Innovative Medicines Canada, 'Code of ethical practices, annotated version 2022' available at: innovativemedicines.ca/wp-content/uploads/2022/01/2022-Code-of-Ethical-Practices-EN-final.pdf.

4 Food and Drugs Act, CRC, c 870, s 2.

5 Health Canada, 'Guidance on distinction between advertising and other activities for health products' available at: canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/actv_promo_vs_info-eng.pdf (the 'Distinction Guidance').

6 PAAB, 'Gating Mechanisms for HCP Digital Assets' available at: paab.ca/resources/gatingshortdoc/#:~:text=The%20primary%20licence%2Dbased%20HCP,HCP%20type%20in%20that%20province.

7 Distinction Guidance, see n 5 above).

8 Health Canada, 'Therapeutic Comparative Advertising: Directive and Guidance Document' available at: canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/therapeutic-comparative-advertising-directive-guidance-document.html.

9 *Ibid*.

10 Regulated Health Professions Act 1991, SO 1991, c 18 (RHPA).

11 Medicine Act 1991, SO 1991, c 30.

12 Distinction Guidance, n 5 above.

13 College of Physicians and Surgeons of British Columbia, 'Promotion and Sale of Medical Supplies and Devices' available at: cpsbc.ca/files/pdf/PSG-Promotion-Sale-Medical-Supplies-Devices.pdf; and 'Conflict of Interest' at: cpsbc.ca/files/pdf/PSG-Conflict-of-Interest.pdf.

14 Ad Standards Guidelines, 5.1; PAAB Code 3.1.

15 *Ibid*.

16 FDR C.01.048.

17 IMC, s. 17. FDR C.01.048.

18 *Ibid*, s 17.3.3.4.

19 *Ibid*, s 16.1.3.

20 *Ibid*, s 16.1.1.

21 *Ibid*, s 16.1.1.

22 *Ibid*, s 16.2.

23 College of Physicians and Surgeons of Ontario, 'Physicians' Relationships with Industry: Practice, Education and Research' available at: cpso.on.ca/Physicians/Policies-Guidance/Policies/Physicians-Relationships-with-Industry-Practice (CPSO, 'Relationships with Industry').

24 CPSO, Relationships with Industry, s 11.

25 *Ibid*, ss 13–15.

26 IMC, s 9.2.5.

27 *Ibid*, s 9.2.5.

28 *Ibid*, ss 9.2.5 and 10.1.3.2.7.

29 *Ibid*, s 9.2.8.

30 CGPA, s 10.1.

31 Distinction Guidelines, p 3.

32 *Ibid*, p 4.

33 *Ibid*, s 12.2.1.1.

34 *Ibid*, s 12.2.2.1.

35 *Ibid*, s 12.2.2.1.

36 Distinction Guidelines, pp 10-11.

37 CPSO, Relationships with Industry, ss 13–15.

38 IMC, s 9.11.

39 *Ibid*, s 9.2.1.

40 *Ibid*, s 9.2.5.

41 *Ibid*, s 10.1.

42 *Ibid*, s 9.2.2-4.

43 Distinction Guidelines, p 12.

44 IMC, s 15.2.1.

45 *Ibid*, s 15.2.3.

46 Health Sector Payment Transparency Act 2017, SO 2017, c 25, Sch 4.

47 CPSO, Relationships with Industry; CPSBC, Conflict of Interest.

48 See: Health Product Advertising Incidents Database.

49 Competition Act, RSC, 1985, c C-34, s 54 and FDA, ss 74.01 and 74.011(1).

50 *Ibid*.