



Regulating Advertising of Health Products

Health Canada sets the standards for health product advertising material in Canada to help advertisers produce messages that are not false, misleading or deceptive.

While it is the responsibility of Health Canada to administer the *Food and Drugs Act* and related *Regulations*, it is the responsibility of market authorization holders (manufacturers and distributors) to ensure that their advertising complies with the relevant legislation and regulations.

Health Product Advertising

Health product advertising is considered to be any representation, by any means (e.g., broadcast, print, Internet), for the purpose of promoting directly or indirectly the sale or use of any health product.

Only health products that have been authorized for sale by Health Canada may be advertised in Canada, and specific regulatory provisions apply to advertisements of prescription and non-prescription drugs, and natural health products directed to consumers and health professionals.

Preclearance Process Overview

Industry compliance with the preclearance of advertising is voluntary, and Health Canada strongly encourages all market authorization holders to have the advertising material for their authorized health products 'precleared' prior to dissemination.

Independent advertising preclearance agencies (APAs) provide 'copy review' services to advertisers and advertising agencies to help ensure that the promotional products, in all media, meet the relevant regulatory requirements and APAs advertising codes. Health Canada provides guidance documents and policies in support of meeting these requirements.

"Approved" advertising is assigned an approval number and/or authorization to use the APA logo or seal/mark, which signifies that the advertising has been reviewed and, in the view of the APA involved, complies with the applicable legislation, regulations, and APA codes.

Health Canada may intervene in numerous situations:

- when an advertisement poses a significant safety concern;
- in the event that a resolution is not achieved through the independent agency's complaints mechanism;
- when a complaint relates to the advertisement of a prescription drug to the general public; and
- when an unauthorized health product is promoted.

Intervention measures may include issuance of regulatory letters, requests for corrective measures or discontinuation of advertisements, seizure of non-compliant advertising materials, or issuance of a risk communication such as a Health Canada advisory or recall.

Advertising Preclearance Agencies

Advertising preclearance agencies must possess and make publicly available in both official languages the policies, procedures and standards they use to ensure that their services comply with Health Canada's requirements.

Additional requirements include:

- an annual reporting system of preclearance activities;
- processes for complaints resolution, adjudication and self-regulatory sanctions;
- proof of skills and core competencies;
- a process to ensure use of only current Health Canada Terms of Market Authorization;
- a system to notify Health Canada of required cases;
- evidence of independence and neutrality;
- performance evaluation and marketplace monitoring capacities; and
- post-publication/post-broadcast audits of the marketplace influenced by its preclearance advice.

Advertising Standards Canada (ASC) and MIJO, formerly Broadcast Clearance Advisory, have attested to meeting Health Canada's recommended public attestation criteria to review and preclear advertising material for non prescription

drugs and natural health products directed to consumers. The Pharmaceutical Advertising Advisory Board (PAAB) is recognized by Health Canada to review and preclear advertising material for prescription drugs and other health products directed to health professionals. Both ASC and PAAB provide advisory opinions on messages directed to consumers for prescription drugs and on educational material discussing a medical condition/disease to ensure that they meet regulatory requirements.

Complaints about advertisements

The first route for adjudication of complaints about advertisements is through the advertising preclearance agencies. Complaints related to consumer advertising of non-prescription drugs and natural health products are directed to ASC or MIJO. Complaints related to advertising of prescription drugs and other health products to health professionals are directed to PAAB. Complaints related to direct-to-consumer advertising of prescription drugs and those for unauthorized health products are directed to Health Canada.

Roles of Health Canada and Advertising Preclearance Agencies

Lead	Roles
Health Canada	<ul style="list-style-type: none"> Set minimum standards in health product advertising by establishing terms of market authorization; developing regulations, guidelines and policies; overseeing regulated advertising activities, and bringing standards to attention of advertising preclearance agencies. Review and process complaints for health product advertising: a) that contravenes the <i>Food and Drugs Act and Regulations</i> and presents a significant health hazard, b) in the event that resolution is not achieved through the independent advertising preclearance agencies' complaints mechanisms, c) when a prescription drug is illegally advertised to the general public, or d) when an unauthorized health product is promoted.
ASC and MIJO	<ul style="list-style-type: none"> Review and preclear non-prescription drug and natural health product advertising material directed to consumers prior to dissemination. Administer complaints and appeals procedures, related sanctions and remedial measures per established standards and procedures.
PAAB	<ul style="list-style-type: none"> Review and preclear health product advertising material directed to health professionals prior to dissemination. Administer complaints and appeals procedures, related sanctions and remedial measures as outlined in the PAAB Code of Advertising Acceptance.