ASC Clearance Services

DTCI GUIDE

About this Guide

This guide will help you develop Direct-to-Consumer Information materials about disease states and treatment options that comply with the Health Canada Policy: *The Distinction Between Advertising and Other Activities*. Follow the "Tips and Traps" to help you navigate through the requirements before submitting your DTCI material to ASC Clearance Services for review.

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DTCI GUIDE – BROCHURES & WEBSITES

How can you make sure your Direct-to-Consumer Information (DTCI) materials (e.g. brochures, websites and help-seeking announcements) meet the criteria set out in the Health Canada Policy: *The Distinction Between Advertising and Other Activities*[1]? Use the guidance provided below.

The *Food and Drugs Act* 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."

So, to ensure that your material is indeed "information" (i.e. nonpromotional) and not "advertising" (i.e. promotional), no element can directly or indirectly promote the sale of a drug. Follow the "Tips and Traps" to help you navigate the road between advertising and information. It all comes down to presenting factual information about a disease state and its authorized treatments in an objective and balanced manner.

BROCHURES & WEBSITES

	Parameter	Guideline	TIPS and TRAPS
1	*Factual*	Present all information in a factual, objective manner.	See "Tips" under "Authorized" (#3) and "Balance" (#5).
2	*Objective*	Discuss various aspects of the disease and its symptoms.	**TIP:** All disease-related statements (e.g. incidence, age of onset, symptoms, etiology and prognosis) must accurately reflect the available medical literature.
		Include discussion of various treatment options.	**TIP:** When drugs are mentioned, provide balanced information. **TRAP:** If only one drug treatment option is available, the message is promotional.
3	*Authorized*	**Authorized Drug Products** When drugs are mentioned, only those products authorized by Health Canada for the disease state in question can be discussed.	**TIP:** All claims must be consistent with the Health Canada Terms of Market Authorization. **TRAP:** Unauthorized "off-label" uses of drugs (i.e. prescription and nonprescription drugs, including natural health products) may not be mentioned, even if documented in medical or lay press.
		Indication Communicate the relevant Health Canada authorized indication for each product accurately.	**TRAP:** Avoid oversimplifying the indication (e.g. do not leave out important information about risk, disease severity or defined patient populations).

[1]This Guide is intended to complement the Health Canada policy *The Distinction Between Advertising and Other Activities* (2005).

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	Parameter	Guideline	TIPS and TRAPS
4	*Unauthorized*	**Unauthorized Drug Products** Limit the discussion of an investigational drug product to mentioning that research is underway in a particular area. Indicate the current regulatory status.	**TRAP:** Avoid mentioning unauthorized drugs that may be available through the Health Canada Special Access Programme.
5	*Balance*	**Drug and Non-Drug Options** Ensure available treatment options discussed are treated equally.	**TIP:** It's all about equality. Treat all options consistently. Address the same points for each treatment option (e.g. if duration of action is mentioned for one option, it must be mentioned for all of them). **TRAP:** Avoid highlighting or overemphasizing a particular drug or class of drugs through extensive detail that isn't afforded to other options. **TRAP:** Avoid excessive repetition of a particular drug name or use of special fonts or graphic treatments.
		Safety and Side Effects Provide information about risks (i.e. safety information, side effects). Ensure a similar type and quality of information is presented for all treatment options.	**TIP:** Risk information (i.e. precautions, warnings, side effects) must be presented for all treatment options. **TRAP:** Avoid downplaying the serious side effects. **TRAP:** Avoid listing serious side effects for competitor's drugs and only minor side effects for sponsor's drug.
		Language Use neutral and objective language. Stick to the facts.	**TRAP:** Avoid superlative, comparative or pejorative terminology (e.g. special, newer, first line, latest, traditional, older, breakthrough).
		Visuals Use a consistent visual layout across all treatment options.	**TIP:** If your campaign includes both DTCI and DTCA, the look and feel (e.g. colours, fonts, layout, and actors/models) must be different. This will help ensure the consumer cannot link the advertised prescription drug product to its indication, which contravenes Section C.01.044 of the *Regulations*. (See Health Canada's Policy Statement: *Advertising Campaigns of Branded and Unbranded Messages)* **TRAP:** Avoid graphics or layouts that highlight or draw attention to a particular drug treatment option.

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	Parameter	Guideline	TIPS and TRAPS
6	*Sponsorship*	Know that it may be acceptable to add a manufacturer's logo to a balanced DTCI piece in some cases.	**TIP:** The more balance you bring to a DTCI piece, the more likely it is that the piece will be considered informational. Declaration of sponsorship of an information piece by a drug manufacturer does not in and of itself render the piece promotional. **TIP:** While the mention of the sponsoring drug manufacturer is acceptable, it should be limited to a simple sponsorship statement (i.e. brought to you by company X).
7	*Hyperlinks*	Ensure there is no brand-specific information on a hyperlink.	**TIP:** Links to independent 3rd party health information websites are generally acceptable (e.g. Heart and Stroke Foundation website). **TRAP:** Avoid linking a disease information site to a drug product or pharmaceutical manufacturer's website.
8	*Visuals/Audio*	Provide all visuals and/or audio.	**TIP:** For a faster ASC review process, provide actual images rather than "for position only" images.
9	*References*	Provide ASC with annotated reference materials to support information/claims within the DTCI piece.	**TIP:** Send references (full text) electronically. Highlight or underline pertinent sections. **TIP:** Give each reference a unique identifier, and use that identifier consistently throughout the submission (i.e. electronic or hard copy file name should correspond to the reference identified in the text). **TIP:** Double-check to make sure that the portion of the reference that is highlighted or underlined supports the relevant information/claim.
		Ensure that statements/claims within the DTCI piece accurately reflect the reference provided.	**TRAP:** Don't omit relevant information (e.g. be sure to include qualifiers such as "*estimated* incidence," "*thought to* act by..."). **TRAP:** Avoid extrapolating the data beyond its scope (e.g. a disease-incidence rate from a study done in American Hispanic males cannot be extrapolated to the general Canadian population).

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	Parameter	Guideline	
10	*Sponsor Attestation*	Provide a signed attestation from your corporate Medical, Regulatory or Compliance Officer confirming that: • material submitted for ASC review has been evaluated to ensure the product claims are consistent with the Health Canada authorized Product Monograph, and • the non-product claims are supported by the reference materials provided.	**TIP:** Include the attestation with the initial submission to avoid delays. ASC's evaluation cannot proceed until the attestation is received. Submissions without attestations will be placed in "Pending" status.
11	*Submission Completeness*	Include all sections of the DTCI piece that will be available to the consumer (e.g. website Privacy Policy and Terms & Conditions, downloadable brochures/questionnaires etc.) in your submission.	**TIP:** Be sure your submission package is complete. If content is missing, the review process will be prolonged.
12	*Related Campaign Components / Companion Pieces*	Ensure all DTCI campaign components/ companion pieces (e.g. 1-800 line, brochure, website, information) are nonpromotional in nature.	**TIP:** Send all DTCI companion pieces to ASC for review. If materials are cross-referenced, ASC will be unable to finalize the review of the original DTCI submission until the companion pieces are reviewed and are determined to be acceptable.
13	*Resubmits*	Check to ensure you've made all requested changes and/or addressed analysts' questions.	**TIP:** Provide a rationale and/or additional references if a requested change is not made. **TRAP:** If ASC comments are not addressed, this will result in resubmission requests and review delays.

DTCI GUIDE – HELP-SEEKING ANNOUNCEMENTS

Help-seeking announcements invite consumers to seek information about a specific medical condition or set of symptoms from a physician or healthcare professional or an alternate source of information (e.g. a 1-800 telephone number or consumer brochure).

Here is an example of a typical help-seeking announcement:
"If you suffer from the following symptoms, you may have condition x. Ask your doctor or call 1-800 for more information."

We've included a few "Tips and Traps" specific to help-seeking announcements since these messages can easily become promotional in nature.

HELP-SEEKING ANNOUNCEMENTS

	Parameter	Guideline	TIPS and TRAPS
1	*Identification of Drug*	Ensure that no specific drug is directly or indirectly identified.	**TRAP:** Avoid indirectly identifying a specific drug by using unique identifiers such as: - dosage form - mechanism of action - packaging - indication - route of administration - dosage schedule - colour schemes or graphic elements that resemble the sponsoring manufacturer's prescription drug product branding
2	*Identification of Manufacturer*	Ensure that no drug manufacturer's name is included.	**TRAP:** Avoid indirectly identifying the manufacturer through elements such as logos.
3	*Campaign Components*	Ensure all DTCI campaign components/campaign pieces (e.g. 1-800 line, brochure, website, information) are nonpromotional in nature.	**TIP:** Please remember that all related consumer-directed companion pieces (e.g. newsletters, e-mail updates, etc) should be submitted for review. **TRAP:** Avoid links to branded or corporate websites, as these can lead to identification of a specific drug and/or its manufacturer.

ASC COPY CHECK LOGO AVAILABLE

ASC Copy Check

Reviewed for compliance with Health Canada's Policy *The Distinction Between Advertising and Other Activities*

ASC's DTCI Copy Check Logo can be included in DTCI materials that ASC Clearance Services has evaluated as complying with the Health Canada Policy: *The Distinction Between Advertising and Other Activities*. All DTCI message sponsors are encouraged to use this logo once DTCI messaging has received final review by ASC. Continuing use of this logo is permissible for as long as the material remains compliant.

DTCI GUIDE – SOCIAL MEDIA

Social media may be used for DTCI, but the same rules apply as they do for traditional media. Here are ASC's tips to help ensure that your DTCI social media sites start and remain compliant.

1	*Nonpromotional*	Start nonpromotional. Ensure that the framework for your social media site is consistent with the Health Canada Policy: *The Distinction Between Advertising and Other Activities*.
2	*Internal vetting*	Use your designated corporate mechanisms for internal vetting (e.g. Regulatory, Medical, Compliance, Legal) prior to going live.
3	*User generated content*	Recognise the inherent challenges of User Generated Content (UGC). UGC can quickly move a site out of compliance.
4	*Administrative controls*	Understand and use the social media platform's administrative controls to manage the level of UGC that will be posted, as well as postings that will require removal.
5	*Transparency*	Be transparent with consumers through the use of disclaimers (i.e. Let users know that content will be monitored and may be removed to maintain compliance).
6	*Monitoring*	Monitoring and taking corrective action are the keys to ensuring sites remain compliant. Monitoring should be proactive and regular. It takes only one non-compliant UGC to move a site from compliance to non-compliance. The frequency of monitoring should be determined based on the volume and nature of UGC. **Note:** Be sure to monitor for discussion of off label uses and adverse events. These should be promptly removed from the site. Report all adverse events to Health Canada in accordance with the Guidance Document: *Reporting Adverse Reactions to Marketed Health Products*.
7	*Preclearance*	Submit your DTCI social media sites to ASC for review to help ensure they are compliant.

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Advertising Standards Canada is the national independent advertising industry self-regulatory body committed to creating and maintaining community confidence in advertising. ASC members – leading advertisers, advertising agencies, media organizations and suppliers to the advertising industry – are committed to supporting responsible and effective advertising self-regulation.

Through ASC Clearance Services, ASC reviews advertising to facilitate compliance with specific laws and regulations in five regulated categories – alcoholic beverages, children's, consumer drugs, cosmetics, and food and non-alcoholic beverages.

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