ASC Clearance Services

DTCA R_X CHECKLIST

About this Checklist

This checklist will help you develop Direct-to-Consumer Advertising for Prescription Drugs that complies with Section C.01.044 of the *Regulations* under the *Food and Drugs Act*. When you have successfully completed the checklist, you are ready to submit your advertisement to ASC Clearances Services for review.

Ad Standards™

DTCA R_X CHECKLIST

1	*Product (Rx)*	**Is the advertising material being submitted to ASC Clearance Services for review directed to consumers concerning a prescription drug product (Rx)?** If "YES": Go to question 2. If "NO": The advertising material is not reviewable under the DTCA Rx framework.
2	*Health Canada authorization 'required' before selling Rx product*	**Has Health Canada authorized the Rx product for sale in Canada?** If "YES": Go to question 3. If "NO": The advertising material cannot be reviewed by ASC Clearance Services. (Section 9(1) of the *Act*; Section C.08.002 of the *Regulations*.)
3	*Intended Audience for the Advertising*	**Is the advertising material directed to healthcare professionals; OR is the advertising material to be disseminated by healthcare professionals to patients?** If "YES": The advertising material is not reviewable under the DTCA Rx framework. If "NO": Go to question 4.
4	*Definition of Advertising*	**Does the advertising material qualify as "an advertisement" as defined in the *Food and Drugs Act*?** If "YES": Go to question 5. If "NO": The material is not reviewable under the DTCA Rx framework. ASC reviews such material under the DTCI framework, which deals with consumer-directed information concerning health-related conditions and indications. (See Health Canada Policy: *The Distinction Between Advertising and Other Activities* and *ASC DTCI Guide*.) **Note:** The *Food and Drugs Act* defines an advertisement 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." (Section 2 of the *Act*)
5	*Identifying Rx Products in Advertising*	**Does the advertising material identify the Rx product?** If "YES": Go to question 6. If "NO": The material is not reviewable under the DTCA Rx framework. Consult the *ASC DTCI Guide*.
6	*Drug Classification: Schedule F*	**Is the product a Schedule F Drug?** If "YES": Go to question 8. If "NO": The advertising material is not reviewable under the DTCA Rx framework. **Note:** C.01.044 (1) of the *Regulations* under the *Food and Drugs Act* states: "Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug."

7 *Drug Classification: Schedule D*

Is the product a Schedule D Drug?

- If "YES": While the advertising material is not reviewable under the DTCA Rx framework, ASC will review such advertising for consistency with the pertinent provisions of the *Food and Drugs Act and Regulations* and Health Canada's Guidance Document: *Fair Balance in Direct-to-Consumer Advertising of Vaccines*.
- If "NO": Go to question 8.

Note: While Schedule D Drugs (e.g. vaccines and insulin) are not subject to the prohibitions cited in C.01.044(1) of the *Regulations*, and may be advertised to consumers, such advertising is subject to the relevant provisions of the *Food and Drugs Act and Regulations*.

8 *Advertising in non-Canadian media*

Is the advertisement intended to appear in foreign media?

- If "YES": Advertisements appearing in foreign media are not subject to Canadian regulatory requirements and cannot be reviewed under the DTCA Rx framework.
- If "NO": Go to question 9.

Note: Foreign media are media that originate outside Canada and contain the advertising in question. This includes commercials that air on US television stations; and printed advertisements that appear in foreign magazines that are sold in Canada.

9 *Stating or implying the indication*

Does the advertisement directly or indirectly communicate the product's therapeutic indication(s)?

- If "YES": Advertisement is non-compliant and will be rejected.
- If "NO": Go to question 10.

Note: Any such implication or representation may be found in:
(a) audio (music, voice-over, sound effects); and/or
(b) in video (depictions, attitudes, references, allusions).

10 *Stating or implying product benefits / Going beyond "name, price, and quantity"*

Does the advertisement directly or indirectly communicate a product characteristic or benefit, (e.g. dosing schedule and duration of action)?

- If "YES": Advertisement is non-compliant and will be rejected.
- If "NO": Go to question 11.

Note: Any such implication or representation may be found in:
(a) audio (music, voice-over, sound effects); and/or
(b) in video (depictions, attitudes, references, allusions).

11 *Visually depicting products*

Is the product visually depicted in any way in the advertisement (e.g. pill or pack shot)?

- If "YES": Go to question 12.
- If "NO": Go to question 13.

12 *Identifying indications through product depiction*

Can the product's therapeutic indication possibly be identified by the way the product/package is depicted?

- If "YES": Advertisement is non-compliant and will be rejected.
- If "NO": Go to question 13.

13	*Identifying indication through reference to medical specialists*	**Does the advertisement include any reference, either direct or implied, to any category of medical specialist (e.g. dermatologist, urologist)?** ● If "YES": Advertisement is non-compliant and will be rejected. ● If "NO": Go to question 14. **Note:** Including a reference to a medical specialist may lead to an identification of the product's therapeutic indication.
14	*Concurrent branded and unbranded messages*	**Are there plans to develop and run a concurrent information-only campaign (i.e. unbranded) about the disease or condition for which this prescription drug product is indicated?** ● If "YES": Go to question 15. ● If "NO": Go to question 16.
15	*Similar treatment of branded and unbranded messages*	**Are there any similarities between the branded advertisement for this product and the unbranded communications regarding the related disease or condition in terms of:** a. theme or context? or b. persons featured? or c. style (e.g. music, font, colours, background)? or d. wording? ● If "YES" to any of the above: Advertisement is non-compliant and will be rejected. (See Health Canada Policy Statement: *Advertising Campaigns of Branded and Unbranded Messages*.) ● If "NO": Go to question 16.
16	*Checklist complete*	**You have successfully completed the checklist and are now ready to submit your advertisement to ASC Clearance Services for review.** **To submit online, go to www.adstandards.com/clearance**

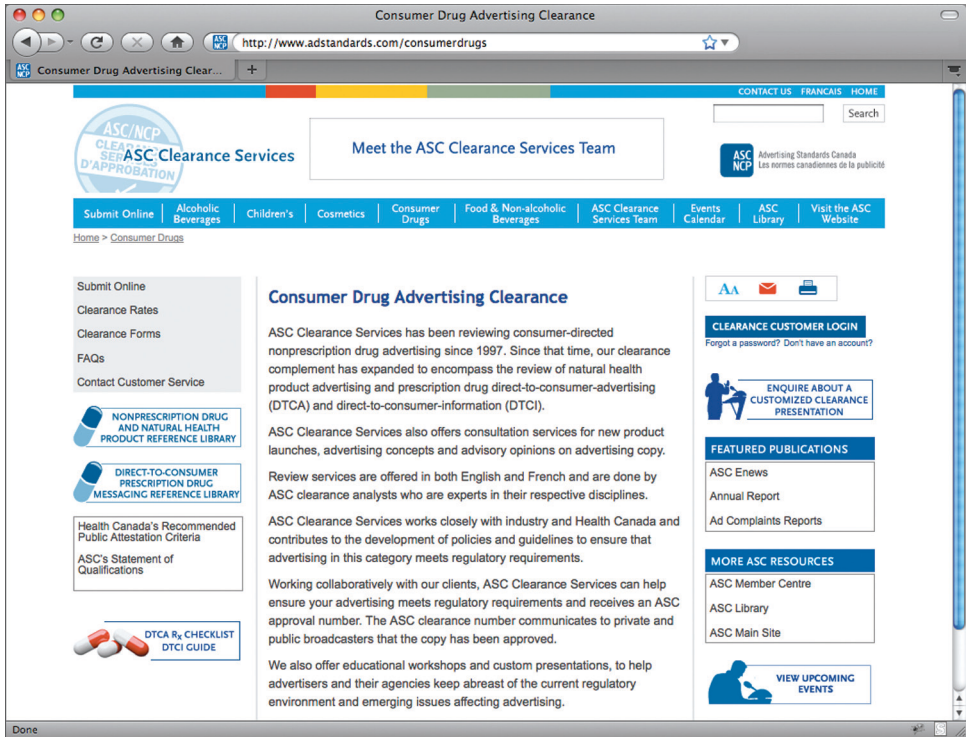
DTCA R_X CHECKLIST – SOCIAL MEDIA

Using social media for DTCA Rx is challenging. Apply the following ASC tips to help ensure compliance.

1	*Limited to name, price, quantity*	Ensure that the company generated content is consistent with Section C.01.044 of the *Regulations* under the *Food and Drug Act* (limited to name, price, quantity).
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). Because UGC can quickly move a site out of compliance, consider locking the page or confining UGC to votes, contests, quizzes or other limited response mechanisms. Remember the owner of a social media site is responsible for all content, including UGC.
4	*Administrative controls*	Understand and use the social media platform's administrative controls to manage the kind 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*	Monitor and remove non-compliant content to maintain consistency with Section C.01.044 of the *Regulations*. 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 allowed.
7	*Preclearance*	Submit your DTCA Rx social media messages to ASC for review to help ensure compliance.

Visit Us Online

Visit the Consumer Drug Advertising Clearance section on our web site at www.adstandards.com/consumerdrugs to meet our team of analysts and to learn about developments in consumer drug advertising clearance and ASC Clearance Services presentations and workshops.



Ad Standards™

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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