

ASC Therapeutic Comparative Claim Review Process
(review time estimate: 6 to 8 weeks)

- 1) Advertiser provides to ASC:
 - (a) Advertising copy/visuals including the therapeutic comparative claim
 - (b) Completed ASC Therapeutic Comparative Advertising Submission Requirements Checklist
 - (c) All required supporting documentation including four (4) copies of the supporting clinical data
 - (d) Name of any clinical reviewer on ASC's Roster who should not be selected to review the data due to possible conflict/bias
 - (e) Clearance fee initial deposit of \$7500*
- 2) ASC selects three non-conflicted reviewers and confirms their availability to review the data within the next 30 days, and commissions an independent literature review.
- 3) ASC reviews file for completeness and evaluates the comparative advertisement as per "Part I: Directive" section of the Therapeutic Comparative SOPs. (7 business days):
 - (a) If the submission is incomplete, the entire review is suspended; and the advertiser is so notified and requested to provide the missing information within the next 30 days.
 - If the missing information is not submitted within 30 days, ASC closes the application file and returns all materials to the advertiser.
 - (b) Once ASC is satisfied the advertisement meets Health Canada (HC) Directive Requirements 1 through 4, copies of the clinical data, SOPs, and results of the literature review are forwarded to the clinical reviewers for their evaluation to determine compliance with HC Directive Requirement 5.
- 4) Each clinical reviewer independently evaluates the clinical data as per the criteria set forth in HC Guidance Document and relevant ASC SOP. **Note:** Reviewers' requests for additional information/clarification regarding the data will be handled through ASC.
- 5) Concurrent with external review, ASC evaluates the advertisement to determine compliance with HC Directive Requirement 6 (on the assumption that the claim is valid) and other ASC and HC Guidelines.
 - ASC notifies the advertiser of any issues unrelated to the therapeutic comparative claim(s).
- 6) Upon completing their evaluation, clinical reviewers provide results of their review to ASC.
- 7) An approval number will be assigned to the **claim** if all three clinical reviewers determine that the evidence supplied by the advertiser to substantiate the claim is conclusively based on and satisfies the Directive requirements. **Note:** Approved claims can be used in subsequent advertising depending on the context. The claim approval is valid until it is determined that contrary evidence disproves the validity of the claim. In this event, the claim approval number is revoked.
- 8) An approval number will be assigned to the **advertisement** if ASC is satisfied that the approved claim, as expressed in the advertisement, and the other elements of the advertisement meet all ASC criteria for approval.

*The \$7500 deposit will be applied toward the total cost of the review. Fees are calculated based on ASC internal and external review costs. ASC will provide a fee estimate to the advertiser after external review requirements are determined, and proceed with review upon written authorization from the advertiser.