

Further to consultation with Health Canada, exclusivity claims for outcomes listed in indications (e.g. “Product X is the first and only product with an indication that lists outcome Y”) may be acceptable in advertising. Conditions for acceptance include:

- The indications/outcomes are meaningfully different
- Disclosure of products with similar indications and/or the same/similar outcomes in their Product Monographs in close proximity in the body copy of the APS

This approach serves to balance regulatory accuracy and ethical issues of transparency.

Example case 1:

Product A is indicated in Condition Y to improve Outcomes I, II and III.

Product B is indicated in Condition Y to improve Outcome I.

In this case, Product A may make the exclusivity claim, “Product A is the only treatment indicated in Condition Y to improve Outcomes I, II and III”. However, it must be accompanied by disclosure that Product B is indicated in Condition Y to improve Outcome I in close proximity in the body copy.

Example case 2a:

Product A is indicated in the treatment of coronary artery disease to reduce the risk of myocardial infarction.

Product B is indicated in the treatment of coronary artery disease to reduce the risk of heart attacks.

In this case, neither product may make an exclusivity claim as the indications are not meaningfully different.

Example case 2b:

Product A is indicated for the treatment of diabetes.

Product B is indicated for the treatment of hyperglycemia.

Similar to example case 2a, neither product may make an exclusivity claim as the indications are not meaningfully different.