Background:

The Notice of Compliance with Conditions (NOC/c) is intended to speed access to potential breakthroughs in serious, life threatening or debilitating diseases such as AIDS, ALS and some cancers. Products accepted with a conditional NOC have shown promising clinical benefit, shown often as effect on surrogate markers such as decreases in helper T cell counts in AIDS. Sponsors have made written undertakings to carry out studies to confirm the clinical benefit in a timely fashion, and these conditions are to be clearly reflected and highlighted in the Product Monograph.

Since the clinical benefits of these drugs have not been confirmed, it is important that advertising for these products clearly and prominently disclose to health professionals the conditional nature of the marketing authorization.

Guidance for advertising:

Details of the conditions are reflected in the Product Monograph, and advertising for all products in the scope of the PAAB Code of Advertising Acceptance must be within the limitations of the accepted monograph or labeling (Section 3.1).
The following clarifies PAAB review practices for NOC/c products:

1. The display portion of advertising must contain a prominent disclosure of the conditional nature of the market authorization and the need to conduct studies to verify its clinical benefit. This means that the NOC/c box should appear upfront, boxed and prominently within the main body copy. Note that the NOC/c box must visually pop-out from the rest of the page/piece content.
2. The display portion of advertising must be consistent with the specific restrictions or conditions specified in the monograph, which inter alia will require clear disclosure of any statements in the monograph or labeling that the indication is based on surrogate endpoints and that clinical benefit has not been demonstrated.
3. For NOC/c product advertising, studies and/or data which are not presented in the Terms of Market Authorization will not be accepted.

Examples for presenting the NOC/c:

The following copy should be captured on the front cover, or at product first mention in a piece, for a product with only an NOC/c indication:

> *Product X ™, indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are refractory to both a PI and an IMiD, has been issued marketing authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for Product X ™ please refer to Health Canada's Notice of Compliance with conditions - drug products web site (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php).*

Alternatively, the abbreviated boxed copy (seen below) must appear **in the upper right corner** (in prominent body copy) accompanied by the complete indication and other pertinent copy from the boxed NOC/c:

PRODUCT has been issued conditional marketing authorization pending the results of studies to verify its clinical benefit. Patients should be advised of this conditional marketing authorization.

Multiple indications – NOC and NOC/c
For products with multiple indications where only one (and/or some) indication is an NOC/c, the above should be applied at first mention of the therapeutic category for which the NOC/c indication exists.

Patient Pieces:
Patient pieces should be non-promotional in nature and present information for the patient to adequately understand the product they are taking. As such, should a boxed label be present on an NOC/c product in the patient information section, it should be presented prominently on the cover of all patient information pieces for that product.

Product X ™ is used in the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are refractory to both a PI and an IMiD. It has been approved *with conditions*. This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

In the situation where there is a combination of multiple NOC and/or NOC/c's which cross the same therapeutic category, the copy should be clearly limited to the NOC population. If the copy is broad and could encompass the NOC/c to some degree, the NOC/c would be required to be presented in the piece.

> **Example:** Brand X has an NOC for the treatment of multiple myeloma as monotherapy. It also has an NOC/c for the treatment of stage 3 multiple myeloma after failure on two previous rounds of treatment and in combination with Product Y and Z.
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> The claim *"You've been prescribed Brand X In the treatment of your multiple myeloma"* would encompass both indicated populations to some extent. Therefore, the full NOC and NOC/c would need to be presented within the piece.