Pre-NOC Corporate/Editorial Communications
(NOC expected imminently)

There may be instances where an Advertising/Promotion Systems (APS) contains elements of both corporate and editorial messages. This document discusses these types of APS individually then provides a single Can & Can't list and a single case study applicable to both types.

Corporate APS (Code Section 7.4)

The intent of a pre-launch corporate APS is typically to convey that the manufacturer is committed to conducting research in a specific therapeutic area. These APS must not contain or imply any product claims, nor state or imply that a new product or indication is coming soon, as this could be construed as pre-NOC advertising and thus contravene section C.08.002 of the Food and Drug Regulations. Such messaging whether explicit or implicit, would be rejected.

General guiding principle: The PAAB considers the overall message of the piece. The piece is likely to be compliant with PAAB code if it simply comes across as a corporate message about commitment to research.
Pre-NOC corporate pieces should be submitted to the PAAB for review as they relate to investigational drug research.

Editorial APS (Code Section 7.5)

The intent of pre-launch editorial APS is typically to increase health care professional awareness and understanding of a specific therapeutic area. Although the content relates to a therapeutic area in which the sponsor anticipates imminently having a new health product entrant, these APS should not contain the message that a new product (or indication) is coming soon as this could be construed as pre-NOC advertising and thus contravene section C.08.002 of the Food and Drug Regulations. Such messaging whether explicit or implicit would be rejected.

General guiding principle: The PAAB considers the overall message of the piece. The piece is likely to be compliant with PAAB code if it is simply an editorial piece about physiology or pathophysiology.
Even if pharmacotherapy is not discussed in the ad, pre-NOC editorial pieces should be submitted to the PAAB for review as they relate to investigational drug research. PAAB code 7.5.1 provides some guidance on how such APS are reviewed:

> *Data presentations or any claims such as clinical efficacy, safety, dosage, and administration for products that have not yet been authorized for marketing (pre-NOC) will not be accepted.*

A cautionary note about campaigns

Although this document provides guidance on producing individual pre-NOC editorial and corporate ads, note that creating an entire campaign around such ads could be construed as pre-NOC advertising which would contravene section C.08.002 of the Food and Drug

Regulations. We therefore advise that our clients exercise caution when considering the frequency of messaging and breadth of formats/media used to convey pre-NOC editorial/corporate content.

Corporate/ Editorial Can & Cant's

The following lists of Can & Can't are not meant to cover all possible scenarios. Please call the PAAB office at (905) 509- 2275 if you have any questions.

Item	Can…	Can't…	Rationale/Examples
Corporate claims	…make corporate claims conveying that the manufacturer is investing in research		To ensure compliance with PAAB code. s.7.4 "Company X is committed to new treatment possibilities" is not acceptable "Company X is committed to research in disease Y" is acceptable
Editorial claim	…discuss physiology or pathophysiology		To ensure compliance with PAAB code. s.7.5. See above example
Ad Campaign		…create an entire Ad campaign around a pre-NOC product	Considered pre-NOC advertising; contravenes section C.08.002 of the Food and Drug Regulations
Product claim		…state or imply that a new product, indication or mechanism is coming soon …discuss or imply any product claims	Considered pre-NOC advertising; contravenes section C.08.002 of the Food and Drug Regulations.
Using a new drug name or class pre-NOC (new to Canada not specifically new to the company)		…mention the pre-NOC product(s) or imply that an unnamed product or class of product is coming	Considered pre-NOC advertising; contravenes section C.08.002 of the Food and Drug Regulations.
Drug feature		…mentioned or refer to drug feature (e.g. dose, dosing frequency, kinetics, binding affinity, molecular structure) even if the product is not mentioned	Considered pre-NOC advertising; contravenes section C.08.002 of the Food and Drug Regulations
Efficacy & Safety		... make efficacy or safety claims	**Consider:** Why discuss these parameters when no Health Canada approved drug is available?

Item	Can…	Can't…	Rationale/Examples

Visuals/colours	…continue to use the same visuals/colours in future branded APS ONLY if the pre-NOC unbranded content falls within the limitations of the Terms of Market Authorization (TMA).	…use the same visuals/colours for future branded APS if the pre-NOC unbranded APS is not within the limits of the TMA for branded APS …use branding elements that are utilized in branded APS in other jurisdictions	Visuals/colours would link pre & post NOC APS due to their proximity in time; there is almost always an overlap time where the pre-NOC APS run simultaneously with the branded APS
Disease presentation Examples: 1. specific receptor, if **no approved drug** with that MOA available* 2. specific receptors if an **approved drug** with that MOA available* 3. metabolic pathway, if **no approved drug** with that MOA available* 4. metabolic pathway if **an approved drug** with that MOA available*	…show editorial disease presentations that are purely physiology or pathophysiology based …discuss the normal physiological or pathophysiological nature of the receptor …discuss the MOA in a way that is consistent with those of the approved product in a fair and balanced manner. …discuss the pathway under physiological and/or pathophysiological conditions …discuss the MOA in a way that is consistent with the approved products in a fair and balanced manner	…show editorial disease presentations based on references that mention an unapproved compound …discuss the effects that an exogenous compound would have on a that specific receptor …imply or discuss unmet needs with current therapy in a disparaging manner …discuss implications of modulating the pathway with unapproved exogenous compounds, classes, or MOA	Would suggest that a drug affecting this disease state is coming. **Consider:** Why discuss a drug effect or drug class when no Health Canada approved drug has that effect or belongs to the class? *Availability refers to the availability in Canada not specifically the company
References	…use published, peer-reviewed papers & single studies, as support for discussion of the physiology & pathophysiology.	…use references that promote the pre-NOC drug or its product code.	Publish peer reviewed papers can be used, as the science pertaining to the new MOA is unlikely to have been incorporated into guidelines and/or texts. Use of references that promote the pre-NOC drug or its product code would be considered indirect promotion of the drug.

			Contravenes section C.08.002 of the Food and Drug Regulations
Support material for current medical opinion or practice	…use guidelines or authoritative textbooks	…use review papers and single studies	Contravenes section C.08.002 of the Food and Drug Regulations
Animal studies	…can use animal studies for description of biologic pathways, if it clearly identifies the animal source		

Pre-NOC Editorial Case Study:

(Please note that all aspects of this case are purely fictional)

For years the scientific community has been exploring the effect of the GRP receptor on prostate cancer. GRP is a pivotal receptor involved in stimulating cell multiplication in prostate tissue. Over stimulation has been linked to prostate cancer progression.

For the sake of this case, here is the fictional "cutting-edge" science in GRP receptor molecular biology:

Pathway:
GRP stimulation → release of factor 12 from mitochondria → inhibition of CCL2 → cell division.

The prostate cellular environment in which the GRP receptor is located has made it challenging to develop a pharmacological compound that can bind to that receptor in high enough concentrations while having minimal effects elsewhere in the body. Finally, a company has managed to meet the challenge!! Scotland Bio Tech is expecting their GRP receptor antagonist to be approved by Health Canada within the next 2 months. The drug will be marketed under the name Prostagone. The drug will be approved for use in combination with current standard care. The product manager has high hopes that this will be a breakthrough product. The product will be on the market without competition for at least a couple years. Scotland Bio Tech would like to get a pre-NOC editorial journal ad approved by PAAB as soon as possible. Assume that all claims are completely supported by references (which make no mention of Scotland Bio Tech's compound). Please let the product manager know which of the following can appear in his APS:

1. Mention that Scotland Bio Tech is heavily investing in Prostate Cancer research?
   Yes.

2. Discussion of the epidemiology & pathophysiology of prostate cancer?
   Yes.

3. Discussion of the GRP receptor (e.g. where it is located, its structure, how it normally functions, what goes wrong with it in prostate cancer)?
   Yes.

4. Show the GRP receptor and the cascade of molecular events which occur when it is naturally stimulated?
   i.e. GRP stimulation → release of factor 12 from mitochondria → cell division.
   Yes

5. Show the modified cascade which would occur if the GRP is inhibited somehow?
   i.e. GRP inhibition → no release of factor 12 from mitochondria → reduced cell division. Assume that inhibition does not occur naturally at the GRP level. As such, this would have to be an effect from an exogenous compound.
   No. This pharmacological mechanism of action has not been approved by Health Canada

6. Same as item 5 above but include a statement that the GRP receptor antagonist is doing the effect?
   i.e. GRP inhibition using a GRP antagonist → no release of factor 12 from mitochondria → suppressed cell division.
   No. There are no GRP antagonists which have been approved by H.C. Additionally, this pharmacological mechanism of action has not been approved by H.C.

7. Present the desired implications of this cascade shift (eg: lower rate of tumour growth, prolonged survival)?
   No. The pharmacologic mechanism of action has not been approved by H.C. As such, the association of those drug outcomes to that pharmacologic MOA could not have been approved by H.C.

8. State that Scotland Bio Tech is doing research on a GRP receptor antagonist or on GRP receptor antagonism?
   No. This could be considered pre-NOC promotion of the manufacturer's product as the reader would now know to keep an eye out for a GRP receptor antagonist from this company. The claim should be limited to research done on the disease (as in question #1) rather than research on a drug category for which this particular company does not have a product approved by H.C.

9. Invite doctors to call medinfo for their questions on GRP antagonism?
   No. This would be an indirect way of getting doctors to enquire about one of the company's unapproved products.

10. Invite doctors to keep an eye out for Prostagone?
    No

Three years after the authorization of Prostagone, High Tech Saskatchewan develops a GRP antagonist which will soon be approved by Health Canada for prostate cancer. The drug will be marketed under the name "Prostasize". A product manager for High Tech Saskatchewan wants to ask you the same ten questions. How would you answer given that the MOA is similar to Prostagone?

1. Mention that Saskatchewan Bio Tech is heavily investing in Prostate Cancer research?
   Yes.

2. Discussion of the epidemiology & pathophysiology of prostate cancer?
   Yes.

3. Discussion of the GRP receptor (e.g. where it is located, its structure, how it normally functions, what goes wrong with it in prostate cancer)?
   Yes.

4. Show the GRP receptor and the cascade of molecular events which occur when it is stimulated?
   i.e. GRP stimulation → release of factor 12 from mitochondria → cell division.
   Yes

5. Show the modified cascade which would occur if the GRP is inhibited somehow?
   i.e. GRP inhibition → no release of factor 12 from mitochondria → reduced cell division. Assume that inhibition does not occur naturally at the GRP level. As such, this would have to be an effect from an exogenous compound.
   Yes. This pharmacological MOA has been approved by H.C. (for the competitor's product "Prostagone"). Inhibition of GRP may therefore be discussed in this unbranded ad (i.e. corporate branded but not product branded).

6. Same as item 5 above but include a statement that the GRP receptor antagonist is doing the effect?
   ie: GRP inhibition using a GRP antagonist → no release of factor 12 from mitochondria → suppressed cell division.
   Yes. The pharmacological classification has been approved by Health Canada. The MOA has been associated with this classification.

7. Present the desired implications of this cascade shift in a non-quantitative manner (eg: lower rate of tumour growth, prolonged survival)?
   Yes. But this needs to be consistent with the outcomes approved by H.C. for "Prostagone" (i.e. refer to Protagone's TMA).

8. State that Saskatchewan Bio Tech is doing research on a GRP receptor antagonist or on GRP receptor antagonism?
   No. This could be considered pre-NOC promotion of the manufacturer's product as the reader would now know to keep an eye out for a GRP receptor antagonist from this company. The claim should be limited to research done on the disease (as in question #1) rather than research on a drug category for which this particular company does not have a product approved by H.C.

9. Invite doctors to call medinfo for their questions on GRP antagonism?
   No. This would be an indirect way of getting doctors to enquire about one of the company's unapproved products.

10. Invite doctors to keep an eye out for Prostasize?
    No