Clarification regarding digitization of APS

Helping healthcare product manufacturers plan for the evolving **COVID-19** operational context

March 2020

In light of recent developments throughout North America relating to COVID-19, some manufacturers are modifying how their drug representatives interact with healthcare professionals. PAAB can help healthcare product manufacturers comply with regulations during this evolving operational context.

Reassurance regarding digitization of print materials

Creation:

Advertising / Promotional Systems (APS) that have undergone pre-clearance for use as print materials can be converted to electronic document types (e.g. PDF) without additional PAAB preclearance or review provided all of the following conditions are met:

1. The entire PAAB approved print document is converted with no change in copy, flow or layout.
   For example, any size changes are directly proportional throughout the APS.
2. No new functionality is added.
   For example, the document is a flat PDF as opposed to a dynamic PDF with new interactive functionality (e.g. menus, pop-ups, accordions, hover-over tool tips, and so on).
3. The print piece is within its PAAB approval period.

Please note that APS digitized in this manner can be distributed to healthcare professionals without informing the PAAB through an FYI notification. These APS should bear the PAAB logo.

Dissemination:

Emails used to distribute digitized APS in an unsolicited fashion DO NOT fall under the person-to-person correspondence exemptions in the PAAB code or advertising regulation exemptions in the Health Canada Policy Document “The Distinction Between Advertising and Other Activities”. These emails with attached APS are subject to PAAB review.

To facilitate the review, we recommend submitting an email template. It can include free text portions for transactional elements (e.g. greeting, date and time of phone meeting, sign-off). This enables the template to be multi-purpose and reusable for a variety of products/APSs. It is important that the individuals sending these emails be trained to not include information about the product, disease, or related company services in those free text portions. These individuals should also be trained to not send product branded and unbranded tools in the same email. The submission of the email template should include detailed information regarding the naming convention for email attachments.

If the intent is for the email template to be used across many brands (and therefore not contain fair balance), the document naming convention should not trigger the addition of fair balance. This means that it should not contain claims or copy that links the brand to therapeutic use. Something like "Brand X efficacy leave behind" would be acceptable.

If the intent is for the email to be brand specific and therefore contain the indication and fair balance, the naming convention can contain the therapeutic use but must still remain claim neutral such as "Brand X PsA efficacy leave behind". Something like "Brand X excellent safety profile" would not be acceptable.

We will work with you to expedite reviews related to your digitization efforts

The PAAB will work with you to expedite reviews for ongoing and new submissions relating to the email templates described above. Should digitization of some of your materials require minor changes to the APS, PAAB will endeavour to work with you to expedite review.