Rules for Agency/Communications Service Providers

All agencies, vendors, organizations or other suppliers (each a "Supplier") retained by Roche Canada to prepare promotional or non-promotional communications and materials intended to be shared outside of Roche (including advertisement, product information, educational materials, training materials, clinical trial recruitment materials, websites, apps etc.) are expected to be familiar with and comply with the following:

1. *Health Canada Requirements.* Supplier will comply with all applicable federal, provincial and local laws, regulations and industry guidelines relating to pharmaceutical promotional regulations, including without limitation:
    a. Sections 9(1), 20(1) and 3(1) of the *Food and Drugs Act.*
    b. Sections C.01.044 and C.08.002(1) of the *Food and Drug Regulations.*
    c. Health Canada's Policy on *The Distinction Between Advertising and Other Activities*, available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/actv_promo_vs_info-eng.php
    d. Health Canada's Guidance on *Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising*, available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/role_apa-pca-eng.php.
2. *PAAB Code:* Where Supplier is preparing promotional materials for medicinal products directed to health professionals, such materials must be prepared in accordance with the Pharmaceutical Advertising Advisory Board ("PAAB") Code of Advertising Acceptance ("PAAB Code"), available at: http://www.paab.ca/paab-code.htm.
3. *General Advertising Standards.* Supplier will otherwise comply with all applicable federal, provincial and local laws, regulations and standards relating generally to promotional activities, including without limitation:
    a. Sections 52 and 74.01(1)(a) of the *Competition Act.*
    b. Advertising Standards Canada's ("ASC") *Canadian Code of Advertising Standards*, located at http://www.adstandards.com/en/Standards/theCode.aspx, and all Interpretive Guidelines thereunder.
4. *AODA Compliance.* Supplier will ensure that all communications and materials are delivered and prepared in a format or manner consistent with the Ontario *Accessibility for Ontarians with Disabilities Act*, including by developing any website content in accordance with the Web Content Accessibility Guidelines (WCAG) 2.0 Level A standard. Starting in 2021, all such websites will need to meet WCAG 2.0 Level AA (other than criteria 1.2.4 (live captions) and 1.2.5 (pre-recorded audio descriptions)). More information may be found at https://www.ontario.ca/page/how-make-websites-accessible.
5. *Rights Clearances.* Supplier will be responsible for clearing all the necessary rights associated with the communications and materials it prepares for Roche, and warrants that such materials will not infringe, misappropriate or otherwise violate the intellectual property, personal information or other proprietary or privacy rights of any third party.
6. ***Copy Approval Requirements***:

a. For all communications and materials developed by Supplier, Supplier shall submit copy to a representative of Roche (who will be designated in advance by Roche) for submission to a review process designated by Roche for Roche approval ("Approved Copy").

    i. Where such communications and materials include pharmaceutical promotional components directed at health care practitioner approval, the review process shall include review by PAAB, an independent agency recognized by Health Canada. The party responsible for submitting a particular promotional component to PAAB shall be assigned in the contract applicable to the project.

    ii. Where such communications and materials include preparing messages directed to consumers and/or directed at providing educational material discussing a medical condition/disease, the review process shall include review by ASC, an independent agency recognized by Health Canada. The party responsible for submitting a particular promotional component to ASC shall be assigned in the contract applicable to the project.

b. Upon receipt of Approved Copy, Supplier shall incorporate all corrections, suggestions, and changes made by Roche. Supplier is responsible for ensuring that the final set(s) of copy/graphics match Approved Copy.

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