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For further information, or for details on sending material to the PAAB for review, please contact:

PAAB

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BACKGROUND INFORMATION ON THE PAAB

VISION

Trusted healthcare product communication that promotes optimal health

MISSION

To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework

VALUES

Integrity, Competency, Credibility, Independence, Excellence, Transparency

MANDATE

The PAAB is an independent review agency whose primary role is to ensure that healthcare product communication for prescription, non-prescription, biological and natural health products is accurate, balanced and evidence-based, and reflects current and best practice

The PAAB also monitors trends in health product advertising and promotion and adjusts its code and practices as required to fulfill its mandate

In granting the PAAB approval and with it the authorization to use the PAAB logo on advertising materials directed to healthcare professionals, the PAAB will adopt the standards specified in this code to all categories of healthcare products [s11] including prescription drugs, non-prescription drugs, biologicals, homeopathy and natural health products (NHP). The PAAB is recognized for making decisions about claims in advertising for healthcare professionals based on the review of scientific evidence. The PAAB will not grant approval or the use of its logo for advertising materials directed to healthcare professionals, patients or consumers that do not meet the standards of evidence of this code, irrespective of the category of healthcare product.

The PAAB reviews materials developed by pharmaceutical manufacturers predominantly for the purpose of advertising or promoting [s11] a product to healthcare professionals and increasing their awareness of that brand. By their very nature, the utility of these materials in providing complete information about a product is limited; however, the PAAB ensures that any information provided about a product is evidence-based and that there is a balance between claims about benefits and possible risks.

Key activities of the PAAB include:

i) Maintaining a Code of Advertising Acceptance, which is approved by representatives of member organizations

ii) Preclearing material prior to dissemination, to ensure claims meet Code standards. The scope of this Code currently includes advertising of Healthcare Products to healthcare professionals and Patient Information provided through healthcare professionals in all media [s11]

iii) The PAAB provides a user fee advisory service on direct to consumer promotional activities regarding the treatment of disease with Federal Drug Schedule F and Schedule D biological drugs that would require a prescription for sale in Canada

iv) Training, adjudicating complaints, administering penalties, reporting of infractions, and other activities to encourage compliance with this code

v) Maintaining liaison with Health Canada, Industry associations and stakeholders to promote an open sharing of information

vi) Consulting widely with stakeholders on matters of policy related to this code

MEMBERSHIP ON THE PAAB

The PAAB was incorporated in 1976 with a multi-stakeholder Board of Directors. The following organizations are members of the PAAB and have appointed official representatives to its Board:

Association of Faculties of Medicine of Canada (AFMC)
Association of Medical Advertising Agencies
Best Medicines Coalition (BMC)
BIOTECanada
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian Association of Medical Publishers (CAMP)
Canadian Generic Pharmaceutical Association (CGPA)
Canadian Medical Association (CMA)
Canadian Pharmacists Association (CPhA)
Consumers Council of Canada
Canadian Association of Retired Persons (CARP)
Consumer Health Products Canada
Fédération des Médecins du Québec (FMOQ)

Health Canada participates as an ex-officio observer on the Board of Directors and acts as advisor to the PAAB, without relinquishing any part of its authority under the Food and Drugs Act and Regulations.

The PAAB is a not-for profit, self-financing organization funded entirely by the fees paid by advertisers for preclearance review (not for the acceptance). A fee schedule and review request registration information are available from the PAAB website www.paab.ca.

1. Scope

1.1 The PAAB Code of Advertising Acceptance applies to all Advertising/Promotion Systems (APS) [s6] in both official languages of Canada (English and French) distributed via all media [s11].

The Code applies to all communications in which claims, quotations and references are made for healthcare products [s11], meaning single entity and compound prescription and non-prescription pharmaceutical products, biologicals, natural health products (NHP), and homeopathy products [s11].

The Code applies to all APS and corporate messages directed to licensed members of the professions of medicine, dentistry, naturopathy, homeopathy, nursing, pharmacy and related health disciplines, to institutions, and to patient information that will be distributed by or recommended by a health care professional. The PAAB provides a user fee advisory service on direct to consumer promotional activities regarding the treatment of disease with Federal Drug Schedule F and Schedule D biological drugs that would require a prescription for sale in Canada. The allowable activities are stated in the Health Canada guideline "The Distinction Between Advertising and Other Activities" and that document is used as the basis for the review. The PAAB advisory review service is recognized and endorsed by Health Canada. The PAAB maintains a liaison with Health Canada regarding the regulation of promotional activities for healthcare products.

1.2 For exemptions refer to Section 6.6.

i) All proposed copy and illustrations for APS intended for distribution to health professionals must be submitted for PAAB review and clearance prior to use.

ii) Both English and French advertising copy must be submitted for clearance, if the same material is to be presented in both languages. APS produced in other languages that are translated from a PAAB approved APS should not carry the PAAB logo and may include a disclaimer stating the item was translated verbatim from a PAAB approved APS.

iii) The sponsoring company shall be responsible for accuracy of translation of APS.

Explanatory Notes

1.1.1 Subject to section 6.6, the Code applies to APS generated by advertisers or their agents, wherein the advertiser's product or a competitor's product is cited by either trade name or non-proprietary name.

1.1.2 No media are exempt as vehicles for the APS. Media include print, audio, visual, audio/visual, electronic and computer means of communication.

Explanatory Notes (in the right column) are intended to clarify the application of the PAAB Code for advertisers, their agents, and PAAB reviewers to help assure consistent interpretation of Code provisions. Interpretation is not limited to the cited examples.

2. General Requirements

Explanatory Notes

2.1 All Advertising/Promotion Systems (APS) [s11] must be accurate, complete and clear and designed to promote credibility and trust. Statements or illustrations must not mislead.

2.1.1 The prescribing information and/or link must be clearly presented within the main message as described in section 7.

2.1.2 In the advertising message portion, the advertiser must present a fair balance [s11] of risk to benefit.

2.2 In all APS for pharmaceutical products, the brand or trade name, the non-proprietary (generic) name and the Federal drug schedule of the product must appear in juxtaposition at least once within advertising copy.

2.2.1 The non-proprietary name must be the same as that cited in the Health Canada authorized Terms of Market Authorization.

2.2.2 The required designations must meet minimum type-size requirements (8 point on 9 point), be in good contrast and be legible.

2.3 APS must be presented in a manner that accurately interprets valid and representative research findings.

2.3.1 Statements that are out of context or distort the conclusions of the author(s) are not acceptable.

2.4 APS must reflect an attitude of caution with respect to drug usage, with emphasis on rational drug therapy [s11] and proper patient selection for the advertised product. The advertising copy should provide sufficient information to permit assessment of risk/benefit in a prominent manner.

2.4.1 The advertising message should include reference to the safety profile consistent with the Health Canada Terms of Market Authorization.

2.4.2 Special warnings, precautions, clinically significant serious adverse events, Notice of Compliance with Conditions (NOC/C) or use limitations cited in the Product Monograph, should be included in the body copy. Boxed messages in Product Monographs for products with NOC/C's should be included in the advertising message. Examples include abuse potential for narcotics or CNS agents, or specific directions for use in special patient groups such as the elderly, pediatric, pregnant women, nursing mothers, women of childbearing age, etc.

2.4.3 With respect to nonprescription healthcare products (i.e. over the counter, natural health and homeopathic products), the fair balance requirement can be met by inserting the following statements into the APS:

i) For Products with a Product Monograph: "Please consult the Product Monograph available at www.websitepage.ca for information to assist in benefit-risk assessment. Always direct the patient to read the label". This should be followed

proximally by a statement that the Terms of Market Authorization is also available upon request through a stated phone number. The indication must appear within the APS.

Note that for electronic APS, the phone number is not required if an electronic link is provided to the Product Monograph. In those cases, the linkage statement should be "Please click here for the Product Monograph available at www.websitepage.ca for information to assist in benefit-risk assessment. Always direct the patient to read the label". The indication must appear within the APS [s7.2.1].

ii) For products without a Product Monograph: "See Warnings, Cautions, and Directions of Use at www.websitepage.ca for information to assist in benefit-risk assessment. Always direct the patient to read the label". This should be followed proximally by a statement that the Terms of Market Authorization is also available upon request through a stated phone number. The indication must appear within the APS.

A link to a website for information on warnings, cautions and directions of use is not required if all relevant text from the Health Canada labeling and product licence is included in the APS [s7.2.1].

Note that for electronic APS, the phone number is not required if an electronic link is provided to this risk information. In those cases, the linkage statement should be "Please click here for Warnings, Cautions, and Directions of Use to assist in benefit-risk assessment. Always direct the patient to read the label". The indication must appear within the APS [s7.2.1].

2.5 The Code does not accept APS that are prejudicial to any gender, race, occupation or patient group, or contravene the ethical values of the health professions.

2.5.1 For additional guidance, the Reviewer has access to supplemental codes and guidelines.

2.5.2 The advertiser must reconsider statements or visual presentations that are potentially offensive, or that may have a 'negative effect' upon company or patient images.

2.6 In company generated copy or quotation(s) from references, no APS may state or imply in absolute terms that any product is 'safe', 'ideal', 'non-toxic', has 'guaranteed efficacy', is 'uniformly well tolerated', or has 'totally predictable action or clinical effect'.

2.6.1 The Code does not accept statements that claim directly, or indirectly, 100 percent clinical efficacy or safety.

2.6.2 The advertiser may make properly supported absolute statements when describing product properties (e.g. pharmacology, actions, kinetics, etc.) if these are presented or grouped separately from the clinical claims section; this avoids any extrapolation of laboratory superiority to imply clinical efficacy or advantage.

2.6.3 The following are other examples of terms, which may not be used, in an absolute or categorical sense or in an unqualified manner: 'avoids', 'eradicates', 'cures', and 'eliminates'.

2.7 APS must not imitate the general layout, text or visual presentation of other pharmaceutical company advertisements in a way likely to mislead or confuse the reader.

2.8 Promotional items offered in advertisements must be related directly to the product or its use(s), or be of practical value to the health professional. Such items must withstand professional and public scrutiny. Items intended for distribution to patients via a health professional must be useful as aids to patients' understanding of, or adaptation to, their condition(s) or for encouraging compliance with recommended therapy.

2.8.1 Such presentations must also conform to individual association codes of marketing practices such as the Rx&D, BIOTECanada, CGPA and by health professional organizations such as CMA or CPhA.

2.8.2 For purposes of this Code 'practical value' shall be limited to compliance with recommended therapy, items useful to the healthcare professionals in their practice, and/or as teaching aids for patients (Rx&D "Code of Ethical Practices" at www.canadapharma.org).

2.9 The sponsor must provide a submission form with the indication of approval of a sponsor company official from the Medical or Regulatory or Compliance department prior to the PAAB submission. This will confirm that the APS is consistent with the approved Terms of Market Authorization and that the claims and/or quotations are supported by references that meet the standards of the PAAB code.

2.10 Authorized Use: An advertisement is misleading if it suggests that a drug is useful in a broader range of conditions or patients than that which had been approved by Health Canada. The segment of patients for whom the product is authorized should set the context for the corresponding benefits. Also, the indication(s) should be stated in a manner that clearly reflects the Terms of Market Authorization.

2.10.1 Any content setting the boundaries for patient selection from the Indications and Clinical Use section of the Product Monograph (or equivalent section of other TMA types[‡]) must be presented prominently among or prior to the first set of marketing benefit claims in the APS. This is only required for the indication(s) promoted within the piece.

‡ The same applies to the recommended use for products with a product licence.

2.10.2 The TMA content "Drug X is indicated for" (or equivalent) must be presented verbatim at least once within the advertising message of the APS.

3. Claims, Quotations and References

Explanatory Notes

3.1 Claims and/or quotations in Advertising/ Promotion Systems (APS) must be consistent with, and within the limitations of, the Health Canada Terms of Market Authorization (TMA) [s11], or prescribing information (PI) [s11] for products with no Product Monograph. Any APS containing direct or indirect product claims [s11] and/ or quotations from the scientific literature must include a complete listing of the scientific references. Labeling must be authorized by Health Canada.

3.1.1 Clinical/therapeutic claims [s11] must be based on published, well-controlled and/ or well-designed studies with clinical and statistical significance clearly indicated. Publication in peer-reviewed journals is usually a good criterion for establishing scientific rigor. Review articles, pooled data, meta-analysis, post-hoc analysis, and observational studies are generally regarded as not being high-level evidence to support claims in drug advertising but data included in the Product Monograph may be acceptable. Additionally, high quality meta-analysis and observational studies can be acceptable. Non-clinical claims must be well supported by evidence.

3.1.2 Unpublished data are regarded as having received independent review when:

i) There is evidence that the final study manuscript has been accepted by the editor of a peer-reviewed journal for future publication.

ii) The data have been reviewed as part of a submission to Health Canada and there is evidence of acceptance indicated by inclusion in the Product Monograph. Citation in the bibliography section of the Product Monograph does not indicate proof of acceptance by Health Canada.

When presented only in the following form, study design and results analyses are not regarded as having been subject to independent review and are not sufficient evidence to be used as reference support for advertising claims:

i) Abstracts presented at conferences and in journal supplements.

ii) Papers published in journal supplements unless the advertiser can demonstrate that the supplement has also been subject to a rigorous peer-review process similar to the attached journal.

3.1.3 Non-evidence based statements such as those from adverse drug reaction reporting systems or testimonials are not acceptable.

3.1.4 Claims based upon laboratory or animal testing reports should be separated and cannot be used to imply clinical significance, unless there is evidence of a valid clinical correlation.

3.1.5 Claims or quotations that are out of context or inconsistent with the conclusions of the cited author(s) will not be accepted.

3.1.6 Footnotes in close proximity may be used to augment information presented in the body copy. Information that is important for a clear and accurate understanding of a product claim must not be relegated to a footnote. Example - an indication or dosage that is limited or that is restricted to a specific group of patients.

3.1.7 With respect to advertising of non-prescription drugs without a Product Monograph, a Senior Regulatory official of the Market Authorization Holder (MAH) may provide an attestation to the PAAB to confirm that a claim has been approved by Health Canada. "Name of the Market Authorization Holder hereby attests that the claim (specific expanded claim) has been authorized by Health Canada for (complete product Brand name)." The MAH may be asked to provide further information.

3.1.8 For Drug Identification Number (DIN) [s11] products transitioned to Natural Product Numbers (NPNs)[s11], the previously accepted Product Monograph will be considered acceptable evidence to support claims made regarding the transitioned Natural Health Product (NHP) [s11]. This does not apply to products whose ingredients [s11] were altered. The previously accepted Product Monograph may not be used to support claims which are inconsistent with the current TMA.

3.1.9 The PAAB can allow the use of sub-group analysis **with specific conditions.**

3.1.10 Secondary endpoints should be clearly identified as such and the primary endpoint of the study should be presented in close proximity when warranted.

3.1.11 The PAAB can allow the use of observational studies **when specific acceptance criteria are met.**

3.2 All reference materials, both published and unpublished (data on file), should be: the most recent available, consistent with current Canadian medical opinion and practice; and be within the limitations of the Health Canada accepted TMA.

3.2.1 Current literature may be used to supplement information contained in the TMA or provide further verification of relevant information in the Product Monograph.

3.2.2 Literature used to support claims contained in the APS must be consistent with the indications, dosage regimens, efficacy and safety information contained in the Health Canada TMA.

3.2.3 Reference to research or ongoing studies may be made in a non-promotional context with no prominence on information that has not been authorized by Health Canada. A study involving off-label use, that has been completed or has been presented at a medical meeting, and includes information that is not included in the Health Canada TMA, must not be mentioned in advertising.

3.3 References cited in the APS must be available to health professionals on request, in English and/or French, either in their original form or translated.

Data on file must be made available to the Commissioner and may be classified as 'Confidential' by the advertiser or the author (pending publication).

A copy of the summary of the Data on File must be provided to health professionals upon request.

3.4 Copies of all reference sources cited in an APS must be provided to the PAAB Commissioner for verification of claims and/or quotations.

3.5 APS containing claims or quotations that emphasize only positive features of a pharmaceutical product, while ignoring significant negative findings, are not acceptable.

3.5.1 The body copy must contain reference to negative findings in a prominent manner.

3.6 Quotations excerpted from published or unpublished scientific literature must be verbatim as presented in the source, and in context. Any deletions should be identified by a series of dots. Deletions of negative findings or other significant information relative to the product and/ or its use(s) will not be acceptable.

3.7 Claims or selected quotations must not refer to other products or different formulations of the same active ingredients unless authoritative data are available to warrant cross-referencing between products [s5.13].

4. Data Presentations

Explanatory Notes

4.1 All data presented in Advertising/Promotion Systems (APS) including: charts, graphs, tables or other reproductions extracted from reference studies or other sources or reproduced by artwork, must be accurate, complete and clear. The source(s) must be identified. Each adaptation of data should be so labeled and the source(s) indicated.

4.1.1 In charts, graphs, tables and other reproductions extracted from the reference studies, the advertiser must not introduce data or imply conclusions that do not appear in the references.

4.1.2 An advertisement should include all pertinent titles, legends and other designations appearing in the reference.

4.1.3 Adaptations of data must be presented in a manner that does not add or subtract from conclusions of the author(s) unless required under a separate provision of the Code.

4.2 Statistics must be presented so as to accurately report the findings and to help make reliable and valid conclusions.

4.2.1 Statistical information should include dosage and the level of significance e.g. confidence interval (CI) and/or p-value, in the presentation. Where confidence intervals and p-values are both available, the manufacturer may decide to report both. The use of 95% CI is encouraged in preference to p-value. Information such as patient numbers, time span, dosage, etc. that are needed to assess the data, may appear in the web link destination containing the prescribing information (PI) [s11].

4.2.2 The advertiser must honor market research company agreements and must submit a release of market share claims from the source of the data. Data should be the most current available, at least within the past six months [s8.4(i)].

4.2.3 Reporting clinical trial results in relative or proportional terms may lead to misinterpretation of the true benefit and degree of a treatment effect. APS which present results using these methods of reporting, namely relative risk (RR) or relative risk reduction (RRR), must also include an indication of the absolute treatment effect. This can be presented as absolute risk reduction (ARR), number needed to treat (NNT) and/or the actual comparative clinical results or rates. The overall presentation should reflect the true magnitude of benefit and not magnify the clinical effect. Undue emphasis on treatment effects in relative terms, by means of graphic presentation or differences in type size, is not acceptable.

4.3 Data presentations which are misleading or ambiguous, or which distort the original meaning or interpretation, either directly or by implication, are in violation of the PAAB Code.

4.3.1 Company-generated charts/graphs, etc. from pooled studies may not be acceptable.

4.3.2 Company-generated charts/graphs, etc. must not distort the conclusions of the author(s) by visual manipulation.

4.4 Reference lists and study parameters may be moved to a web link destination [s11].

4.4.1 A prominent statement within the main advertising message must identify that this content can be accessed at the web link destination. The linkage mechanism may be a URL (e.g. in a print tool) or an electronic link. The URL may be supplemented, but not replaced, by an electronic coding system (e.g. a QR code or a bar code).

4.4.2 The reference list and study parameters are assessed by the PAAB during review of the corresponding APS. A separate review of the link destination webpage is not required where the contents of that page are limited to the following:

- Product logo (without tagline) and/or the corporate logo
- Reference list and/or study parameters
- TMA and risk communications for APS
- An optional link to the post-gate homepage when the web link destination is part of a broader site
- An optional footer containing legal elements such as the privacy policy, terms of use, and contact information

- Optional branding colour scheme (but no images)

Web link destination pages having additional content (whether text or images) are required to be submitted for PAAB review as a separate APS.

4.4.3 Where mandated by the consumer advertising regulations [s6.5.6], the web link destination must either be gated or de-indexed from search engines. If the site is gated, the URL or electronic link promoted in the APS must bypass the gate such that password entry is not required to access these disclosure documents. The URL and electronic link must therefore be promoted only to HCPs.

4.4.4 Reference citation format should be clear and complete. The PAAB may require changes where there is an off label or misleading claim in the title.

4.4.5 When relegated to link destinations, the APS reference list and study parameters must take one of the following forms:

- Different link destinations for each APS:
    - Each link destination contains the reference list and study parameters specific to the corresponding APS
    - The reference numbers and sequence in the link destination match those in the APS
    - Within the PAAB preclearance process for the corresponding APS, the entire list of references and study parameters would undergo PAAB review
- Single link destination common to each of this product's APS:
    - The link destination houses a master list of the references and study parameters used across this product's advertising campaign
    - The reference numbers on the destination webpage match those in the APS (although the sequence will likely differ)

- Within the PAAB preclearance process for the corresponding APS, those references and study parameters relating to the piece are reviewed

- The Market Authorization Holder must remove references and corresponding study parameters from the master list if acceptance of all APS utilizing those references expires

4.4.6 The content on the destination site must be in the same official language as the APS.

4.4.7 The Market Authorization Holder is required to ensure that the link and the destination are maintained for the duration of the period for which traffic is sent to that link/destination or for the period of use of the "originating piece".

5 Comparisons

As part of the PAAB Code, reprinted here in **bolded type** is the text of the Part 5 "Policy" from the Health Canada directive entitled *Principles for Comparative Claims Related to the Therapeutic Aspects of Drugs*.

Consistent with the provisions of Section 9(1) of the Food and Drugs Act, pharmaceutical manufacturers are required to observe the following principles in making claims that compare the therapeutic aspects of drugs:

Explanatory Notes

5.1 The compared drugs/products have an authorized indication for use [s11] in common, and the comparison is related to that use; or, in addition to the common indication for use, a second authorized indication is claimed as an added benefit of the advertised drug, and

5.2 The comparison is drawn between drugs under the same conditions of use [s11], e.g. at equivalent part(s) of their authorized dose ranges (maximum vs. maximum dosage), in a similar population, and

5.3 The claim does not conflict with the Terms of Market Authorization [s11] of the compared products[1], and

5.4 The claim is of clinical relevance [s11] in humans, i.e. relevant to treatment selection, and, where this is not readily apparent, its clinical relevance can be justified by the sponsor, and

5.5 The evidence generated to substantiate the claim is conclusive and based on:

i) **Consideration of all relevant data, and**

ii) **Scientifically accurate, unbiased, reproducible data obtained from studies conducted and analyzed to current scientific standards using established research methodologies and validated end points, and**

iii) **Appropriate interpretation of the data.[2]**

5.6 The claim and its presentation should:

i) **Identify the compared entities[3], and**

ii) **The medicinal use related to the claim where this is not readily apparent[4], and**

iii) **Not obscure the therapeutic use of the advertised product/ingredient[5] [s11], and**

iv) **Not attack the compared drug product(s)/ingredient(s) in an unreasonable manner, and**

v) **Be expressed in terms, language and graphics that can be understood by the intended audience.**

Advertisers are responsible for ensuring that comparative claims that fall within the scope of these Health Canada Principles, meet these requirements. Furthermore, all comparisons must satisfy the requirements of the full PAAB Code, including the following provisions:

5.7 *Comparative claims of efficacy and safety* generally require support of evidence from head-to-head well-designed, adequately controlled, blinded, randomized clinical studies. Open-label studies are generally not considered to be a high level of evidence and are not acceptable if subjective end-points are included in the study. Comparative claims should be relevant to current medical opinion and practice.

5.7.1 Adverse events and clinical efficacy data quoted from two or more Product Monographs or derived from studies that were not head-to-head, are not acceptable support for comparative claims of clinical safety or efficacy. This is due to the fact that factors such as study methodologies, patient populations, dosing and measurement criteria used in the separate trials can vary widely. Furthermore, a side-by-side presentation of these adverse events and

efficacy data, which lack comparability, could leave a misleading impression and does not meet the PAAB Code acceptance standards.

5.8 *Methodologies, endpoints and independent review.* To be considered as evidence, clinical studies must use established research methodologies and validated endpoints. To aid in the assessment of these study parameters, the PAAB looks for evidence that the full study results have been subject to independent review, such as that found by achieving the publishing of study results, including statistical analyses, in a peer-reviewed journal.[6]

5.8.1 Alternatively, unpublished data are regarded as having received independent review when:

i) There is evidence that the full study manuscript has been accepted by the editor of a peer-reviewed journal for future publication, or alternatively when

ii) The data have been reviewed as part of a submission to Health Canada and there is evidence of acceptance (such as inclusion in the Product Monograph)

5.8.2 When presented only in the following form, study design and results analyses are **not** regarded as having been subject to independent review and are **not** sufficient evidence to be used as reference support for advertising claims:

i) Abstracts presented at conferences and in journal supplements.

ii) Papers published in journal supplements unless the advertiser can demonstrate that the supplement has also been subject to an adequate peer-review process.

5.9 *Analysis of data.* To be considered as evidence, results must achieve an acceptable level of statistical significance. Where confidence intervals (CI) and p-values are both available, the manufacturer may decide to report both. The use of 95% CI is encouraged in preference to p-value. The use of 90% CI is acceptable for presentations of pharmacokinetic data. Failure of study results to demonstrate a statistically significant difference in the measured effect is not sufficient to support a claim of equivalence between the treatments studied.

5.10 *All direct and indirect comparisons* must not mislead and be supported by reliable current data [s11].

5.10.1 The following types of claims are subject to the requirements noted:

i) Comparisons of adverse events or efficacy of a product or drug ingredient may be supported by a peer-reviewed, published meta-analysis of data from studies in which the conditions of use of the compared drugs are consistent with those authorized in Canada.

ii) Pharmacoeconomic and quality of life claims must be supported by high-quality studies. Disclosure of study parameters [s5.11] is important for interpretation of results.

iii) For comparisons of non-clinical data (e.g. pharmacokinetics and pharmacodynamics), no direct or indirect clinical conclusions may be made in advertising unless a strong correlation can be established (e.g. where the rate of absorption is a direct measure of the onset of symptom relief).

iv) Price comparisons that imply or suggest therapeutic equivalence are not acceptable. A disclaimer may be appropriate.

5.10.2 The following classes of claims are subject to these requirements noted:

i) Market share and price claims, must be based on and referenced to, current authoritative data and must not state or imply therapeutic equivalence.

ii) Other non-therapeutic product claims [s11], such as taste or packaging, require support from adequate, unbiased and statistically valid data.

iii) Information from two or more Product Monographs on products' properties[7] and on instructions for use or use limitations[8] may be acceptable as side-by-side presentations and in text form. While the Code permits products to be accurately differentiated by these parameters, no clinical significance must be stated or implied where none has been proven, as is required under the Code for any statement. To ensure that clinical significance is not implied, a disclaimer may be required:

"Data from separate Product Monographs; comparative clinical significance has not been proven."

Any such side-by-side presentation or statement must be complete, in that other data relevant to the presentation also contained in the Product Monographs must not be omitted. The presentation or

statement must not be accompanied by a heading that implies an overall comparison of clinical efficacy or safety.

5.10.3 In submitting the claim for review, the advertiser attests that the data is current and does not conflict with the body of evidence in the field.

5.11 *Disclosure of study parameters.* The claim should be accompanied by or linked to disclosure of relevant study parameters that would aid the reader in interpreting the data e.g. patient numbers and p-value and/or confidence intervals (CI). This information should be in prominent type size (a minimum of 8 point on 9 point). In no circumstances would extrapolation of the claim beyond the actual conditions of the supporting studies be acceptable. Information such as study methodology, description of patient type and number, disease severity, dosage range, study sites, etc. may appear with the prescribing information (PI).

5.12 *Context.* Selective data presentations or claims which distort study findings, or which are out of context with study conclusions, are not acceptable.

5.12.1 All advertising is subject to Code requirements for risk/benefit balance.

5.13 *Equivalence.* Bioequivalence claims are based on valid comparative data, normally to standards currently in use by Health Canada. Accurate statements may be made about the interchangeability of products recognized on various formularies. Claims of therapeutic equivalence must be based on valid comparative evidence.

5.14 *Formulation.* Studies using non-Canadian products are not accepted unless the advertised Canadian product is identical (i.e. identical master formula) to the corresponding non-Canadian product used in the original studies. A letter from the sponsor's Medical/Regulatory Department would be required.

5.15 *Scare tactics.* Advertising that induces fear or uses scare tactics to introduce unwarranted concern will not be accepted.

5.16 *Superlatives.* Unless substantiation can be provided, advertisers may not claim or imply that a product has a superlative feature or function (e.g. most effective, least toxic), or is accorded special status (e.g. the standard,

unique). Similarly, advertisers may not, without substantiation, claim or imply superiority or special status for a company, its personnel, services, or product line.

5.17 *Trade Marks.* Copy must acknowledge competitors' trade marks.

1. For drugs subject to Division 8, Part C of the Regulations, the Drugs Directorate Policy: Changes to Marketed Drugs provides guidance on product information changes that require the filing of a Supplemental New Drug Submission, Notifiable Change etc. For drug products assigned a DIN but are not subject to Division 8, Part C of the Regulations, Section C.01.014.4 of the Regulations identifies the product information changes that require a new DIN application, provided the new information does not render the product subject to Division 8, Part C of the Regulations.
2. Extrapolation beyond the actual conditions of the supporting studies is not acceptable.
3. i.e. hanging comparisons such as "better", " faster acting" are unacceptable, as are vague statements such as "compared to the leading brand...."
4. Where the advertised entity has more than one indication for use, it should be clear to which use the claim refers.
5. i.e. the comparative claim should be afforded no more prominence than the therapeutic use.
6. As defined by the International Committee of Medical Journal editors, a peer-reviewed journal is one that has submitted most of its published articles for review by experts who are not part of the editorial staff.
7. e.g. drug pharmacokinetics, pharmacodynamics and pharmaceutical information.
8. e.g. Indications, Contraindications, Warnings, Precautions, and information on dosage, administration and overdose.

6. Advertising/Promotion Systems (APS) Categories

Advertising/ Promotion Systems (APS) must conform to the PAAB Code requirements.

6.1 Journal Advertisement APS

Journal advertisements are designed to promote an advertiser's products to health professionals via the media [s11] of single or multi-sponsored publications.

Journal advertisements must be submitted for PAAB acceptance prior to distribution to health professionals.

Each discrete advertisement in a publication must satisfy the PAAB Code requirements.

A link to the prescribing information (when required) must be clearly identified within the main message as described in section 7.

6.2 Direct Mail APS

Direct mail is designed to promote an advertiser's products to health professionals via

Explanatory Notes

6.1.1 Publications include both print and electronic vehicles.

6.1.2 The PI is an integral part of any journal advertisement.

6.1.3 Advertisements that are displayed in multiple portions over contiguous pages (e.g. over pages 3, 5, and 7) may be deemed to be a single advertisement and reviewed as such provided each part can be easily identified as part of the complete ad.

Portions of advertisements that will not be displayed on contiguous pages will be reviewed as discrete advertisements. The advertiser must inform the PAAB if ad portions will not appear contiguously.

6.2.1 Recognized delivery systems include electronic mail, fax transmissions, and computer networks or programs.

the Canadian postal service or other recognized delivery system(s).

These materials include printed advertising and information brochures, pamphlets, instruction sheets, business reply cards, surveys, etc. and any covering letter(s).

All such materials must be submitted for PAAB acceptance prior to distribution to the health professions.

A link to the prescribing information (when required) must be clearly identified within the main message as described in section 7.

6.3 Detail Aids APS

Detail Aids are designed to help professional representatives promote a company's products and/ or services directly to health professionals. Detail Aids include printed or electronically presented advertising and promotional brochures, pamphlets, information and instruction sheets, point-of-purchase items and exhibits for conferences and other meetings. All such materials must be submitted to the PAAB prior to presentation to health professionals.

A link to the prescribing information (when required) must be clearly identified within the main message as described in section 7.

6.3.1 Audio, audio-visual and computer programs are considered to be electronic detail aids that must be submitted for PAAB acceptance.

6.3.2 For review purposes, the PAAB makes no distinction between leave-behind and non-leave-behind detail aids or representatives' materials.

6.3.3 An APS comprised of a product monograph which has been embellished should not be labeled as "Product Monograph".

6.4 Service-Oriented Vehicle APS

Service-oriented vehicles are designed to contribute to the healthcare professional's/ patient's understanding of a condition or its treatment. Such materials include patient information [s6.6(vi)] for exemptions] that is prepared or controlled by the manufacturer or its agent.

The acceptability of promotional items shall be subject to industry association standards for marketing practices and must be justifiable in the light of professional or public scrutiny.

All original copy and illustrations (or facsimiles) for use in such programs must be submitted to the PAAB for review and clearance.

A link to the prescribing information (when required) must be clearly identified within the main message as described in section 7.

6.4.1 Examples of service-oriented vehicles include anatomical or diagnostic charts, diagrams and models, and medical or scientific tables.

6.4.2 Examples of patient information vehicles are company-controlled patient brochures, videos, internet and other electronic presentations, 1-800 number scripts and sponsor-controlled communications, that patients are directed to by healthcare professionals.

6.4.3 Company controlled or prepared branded patient information is information that contains non-promotional material that is consistent with, and in addition to, the consumer information section of the Product Monograph. The information should focus on educating patients about particular diseases/conditions and optimal use of the product by the patient for whom it has been prescribed.

This information should address patients' expectations through encouraging meaningful dialogue between patient and healthcare professional and supplementing this dialogue with the best available evidence-based statements.

All health product information must be consistent with the Terms of Market Authorization (TMA), and should not contain promotional claims.

The Advertising/Promotional System (APS) could contain additional sources of health information from standard setting organizations. It should be written in clear, understandable and legible language.

<u>Principles for education on optimal use of the product and diseases/conditions:</u>

Principle 1: Clarity of message

Principle 2: Manage expectations

Principle 3: Evidence-based information

Principle 4: Un-biased sources of information

6.5 Internet, Audio, Visual, Audio/Visual (AV), Electronic, Social Media [s11] APS

These systems promote a company's products and/or services to health care professionals, patients and/ or consumers [s11].

A link should be provided to the complete Product Monograph when the activity is distributed as advertising or promotion [s11]. For patient information sites [s6.4] the sponsor may include both the Product Monograph and the "Information to the Consumer" section of the Product Monograph.

The nature and content of online activities depends on the audience that is being solicited. The three audiences that messages or information may be directed to include:

i) Healthcare Professionals (HCP)

ii) Patients

iii) Consumers

The regulatory requirements for the content can vary by the nature of the content of the activity.

6.5.1 These guidelines apply equally to web-sites and other electronic online activities within the sponsor's control or influence where the intended audience is Canadians.

Media covered include, but are not limited to: banner ads, e-mail marketing campaigns, online patient drug therapy adherence programs, search engine marketing [s11] and optimization techniques, social media platforms, networks and bookmarks, widgets, gadgets, mobile platforms and applications [s11], tablet software, blogs, wikis, Really Simple Syndication (RSS) [s11] feeds, CDs, DVDs, computer software, online detailing including but not limited to self-directed HCP or company representative directed, slide programs, video and television, coding systems (e.g. QR) [s11] and other online/Internet media/platforms.

When creating these APS, the sponsor should consider content, target audience and federal drug schedule within all of the requirements of the PAAB Code of Advertising Acceptance.

6.5.2 The name of the pharmaceutical company

The categories include:

i) Advertising

ii) Medical and Disease Information

iii) Education and Learning Programs

iv) Corporate Information

For Federal regulatory requirements, see the Health Canada policy document "The Distinction Between Advertising and Other Activities" available on the Health Canada website.

sponsor should be stated clearly on:

i) Every page of the website controlled by the sponsor

ii) On every sponsored web-page of a site with no access control

Except where regulatory requirements or third party owners prohibit use of the company name.

6.5.3 Preclearance reviews:

Conceptual frameworks including topics and outlines relating to sponsored social media platforms, chat rooms, postings, bulletin boards and other forms of interactive on-line communication programs must be submitted for the PAAB preclearance review. Those elements or portions that are under the direct control of the manufacturer are required to be pre-cleared.

New content added by the sponsor after the original preclearance acceptance should be sent for preclearance review. It is the sponsor's responsibility to ensure that ongoing user-generated content meets all of the PAAB code and federal legal requirements. Corrective comments may be exempt from the PAAB preclearance review if no new content is added.

6.5.4 Linking [s11] advertising to non-advertising can make the content of both delivery systems advertising.

Linking factors include proximity, appearance, sequence, and context.

Third-Party links to websites where entry is in proximity to content that contravenes the PAAB guidelines are prohibited. When a user clicks on a link to leave the sponsor's website a message should appear informing the viewer.

For consumer accessible sites, federal regulatory requirements restrict the advertiser from **influencing** the message environment such that the consumer can easily link **content** from distinct messages which taken together exceed the regulatory requirements for drug advertising.

The sponsor may link to corporate global sites only by linking to the global site home

page. The sponsor should not link to the global site product pages or sections.

6.5.5 **Banner or pop-up ads** that contain either direct or implied product claims must include risk/ benefit fair balance [s11] and be page-linked to the Product Monograph. These ads require the PAAB preclearance review. Only banner ads that meet consumer advertising requirements can be used on consumer accessible sites.

6.5.6 **Access Control**: For physician, patient or consumer access to industry sponsored websites, platforms or networks, the sponsor should provide adequate and sufficient mechanisms to determine the regulatory category of the person requesting the information on-line.

For sites containing content related to prescription products and/or healthcare products promoting the treatment or cure of Schedule A diseases, the mechanism is required to pose a barrier restricting consumers from having access to the sponsored site.

For sites directed at **patients**: sponsors should provide control of distribution of the password allowing entry to the sponsored location. The Drug Identification Number (DIN) is an acceptable password.

For sites directed at **healthcare professionals**: sponsors should provide a well-controlled entry system.

6.5.7 **Privacy**: Sponsors are expected to ensure compliance with federal and provincial laws regarding collection and utilization of personal information. Web-sites must conform to current industry standards for maintaining security, accuracy and privacy of the information on the site and the information it has collected.

6.5.8 **Static Online Content**: Static online content includes information that is made available online but does not allow for a user to modify or comment on the content. This includes web pages that deliver content that is completely controlled by the sponsor.

For promotional content, all the current rules, regulations, policies and guidance that exist for drug advertising and other activities apply equally to online static content and

content delivered via traditional media (e.g. journal ads). This includes but is not limited to, fair balance requirements in the PAAB code and guidelines.

6.5.9 Dynamic Online Content:

There are two types of dynamic online content:

i) Site-generated content (SGC): Content initiated by the sponsor but may be presented to the audience by third party

ii) User-generated content (UGC): Content/dialogue created by users in response to site generated content

The presence of UGC on a sponsored property can render a compliant page non-compliant by the comments that have been made.

For promotional content in areas that are within the sponsor's control, all the current rules, regulations, policies and guidance that exist for drug advertising and other activities apply equally to online dynamic content and content delivered via traditional media (e.g. journal ads). This includes but is not limited to, fair balance requirements in the PAAB code and guidelines.

Terms and Conditions: The sponsor should provide in a clear and accessible manner the terms and conditions for users to engage in UGC on a sponsored site, with clear statements regarding the types of comments that would be removed or modified.

Monitoring the Conversation: Sponsors must monitor the UGC to ensure that compliance is maintained.

6.5.10 Search Engine Optimization [s11]:

Sponsors should not provide the text of a meta data descriptor that contains direct or implied product claims to a search engine that would contravene any federal regulatory requirements for drug advertising. Any descriptor under the control of the sponsor, for patient and/or healthcare professional sites, that include direct or indirect claims, must be submitted for preclearance review. Keywords and other meta data tags that refer to competitor products are prohibited.

The requirements involve the relationship between the metadescriptor, the keyword, and the site/page. The PAAB does not concern itself with the ultimate ranking of organic search results.

Metadescriptors in organic search results for schedule D products may contain claims. They do not require fair balance.

6.5.11 Search Engine Marketing [s11]:

The meta data requirements are the same as Search Engine Optimization with the additional requirement that purchased keywords taken in context with the other material, not exceed the regulations.

The sponsor should not take steps to cause the composite of the user generated keyword, the metadescriptor, the landing page, and the Uniform Resource Locator (URL) [s11] to exceed that which is permissible (e.g. meta tags). Sponsored search ads containing claims must include fair balance.

6.6 The following does not require PAAB Review:

(i) **Information** materials that have been **independently** controlled and prepared, with industry involvement limited to purchase and/or sponsorship of the distribution (example: a textbook).

Meeting Reports of sections of accredited Health Professional Meetings or Continuing Education (CE) [s11] events/activities organized independently of the sponsor of the materials and that are not focused on, or provide emphasis on, the sponsor's product(s) i.e. do not promote the sale of the sponsor's product(s).

See Health Canada guideline "The Distinction Between Advertising and Other Activities" regarding section "Continuing Medical Education (CME)/Scientific Symposia/Exhibits" that states "Moreover, reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific drug may be advertising if they are disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting."

6.6(i)a Please note that these items will be exempt from PAAB review. They may fall under the definition of "advertising" in the Food & Drugs Act and Regulations. See the Health Canada Policy "The Distinction Between Advertising and Other Activities" on the Health Canada web-site. See definition of advertising [s11].

6.6(i)b Materials that are created by the academic organizers of **accredited Continuing Education events/activities** may be distributed at the event or to the registrants of that meeting at a later date.

6.6(i)c If materials are to be distributed after the event to non-participants of the event by a sponsor company, and product **or therapeutic claims** [s11], comparative data or statements regarding the sponsors products are emphasized, the complete document must be submitted to the PAAB for review. The respective roles of the authors and the sponsoring pharmaceutical company must be stated clearly on the title page.

6.6(i)d On exempt materials, the sponsorship statement must not include any listing of single or multiple products.

(ii) **Personal** (person-to-person) correspondence.

6.6(ii)a This exemption applies to single letters carrying a personal response or message.

6.6(ii)b This exemption does not apply to multiple personal letters initiated by the company.

(iii) Government agency correspondence requirements (drug recalls, warnings, etc.) over which the PAAB has no jurisdiction.

(iv) Use of drug name only in a context not linked to therapeutic or promotional messages, other than those listed in s6.6(iv)a in any way.

6.6(iv)a Examples are:

i) Company price lists containing no therapeutic claims, price comparisons or claims of company or product merit, status or issues.

ii) A message comprised only of the words “now on provincial formulary” (or equivalent) in a manner which is not linked to a therapeutic message in any way.

iii) A message of “available at company X”.

iv) A message of “Congratulations to company X on their 30th anniversary – sponsored by Company X makers of product Y”.

v) Packshots are acceptable if no therapeutic claims are visible.

(v) Corporate messages which do not contain product information or lists.

(vi) Patient Information direct from and consistent with the Product Monograph [s6.4], or when the information is solicited by the patient.

(vii) Disease information materials which make no mention of treatment by name, class, or category AND are not linked to healthcare product advertising in any way, are exempt from PAAB preclearance.

7. Disclosure/Prescribing Information Requirements

Explanatory Notes

7.1 Prescribing information (PI) [s11] in pharmaceutical Advertising/Promotion Systems (APS) must conform to the requirements outlined in Section 7.3 of this Code. Indications for use of a pharmaceutical product must conform to the Health Canada authorized Product Monograph, or, if there is no monograph, the accepted PI. If neither of the above exists, the Commissioner will make an evaluation after consultation with the appropriate Health Canada official(s) and clinical consultants.

7.2 PI, when required or when necessary, must form an integral part of the advertising message, which may be accomplished via a reference to a website link in a printed piece or by a direct electronic link to a website.

7.2.1 With respect to non-prescription healthcare products (i.e. over the counter, natural health [s11] and homeopathic products), if all relevant text from the Health Canada labeling and product licence is included in the ad, then prescribing information is not required. Relevant text would include: the medicinal ingredients [s11], the approved use, all cautions & warnings, contraindications, interactions, known adverse reactions and dosing information relating to the use(s) promoted in the APS.

7.3 Advertising with Product Claim [s11] **Link to Terms of Market Authorization**

One of the following must appear prominently within the main advertising message of the APS:

- Electronic link(s) to the current TMA (and Health Canada endorsed risk communications issued since approval of the TMA if relevant)
- URL(s) for a webpage containing the current TMA (and Health Canada endorsed risk communications issued since approval of the TMA if relevant) accompanied by a statement that these documents are also available upon request through a stated phone number

7.3.1 Requirements pertaining to presentation of the link within the APS:

7.3.1a For non-electronic APS, a URL should be presented in the following way: "Please consult the [specify the form of TMA (e.g. Product Monograph)] available at www.websitepage.ca". This should be followed proximally by a statement that the TMA is also available upon request through a stated phone number.

Additional URL statement requirements:

- When a risk communication is included within the link destination, the statement must refer to it. For example, "… consult the Product Monograph and Dear Healthcare Professional Letter available at…"
- When study parameters and/or references are relegated to the link destination as described in section 4.4, the statement must clearly indicate this. For example, "consult the Product

Monograph, study parameters, and reference list available at…"

The URL may be supplemented, but not replaced, by an electronic coding system (e.g. a QR code or a bar code).

7.3.1b An electronic link should be presented in the following way:

"Please click here for [specify the form of TMA (e.g. Product Monograph)]".

Additional electronic link statement requirements:

- When a risk communication is included within the link destination, the statement must refer to it. For example, "…click here for the Product Monograph and Dear Healthcare Professional Letter available at…"

- When study parameters and/or references are relegated to the link destination as described in section 4.4, the statement must indicate this. For example, "…click here for the Product Monograph, study parameters, and reference list available at…"

7.3.2 Requirements pertaining to the web link destination

7.3.2a The following link destinations are acceptable:

- The TMA and the risk communication on the Health Canada website. The requirement relating to the TMA can be met by linking to the appropriate database search engine page (e.g. the Drug Product Database, Licensed Natural Health Products Database). This option may not be available for new products or those having recently undergone TMA revision due to Health Canada delays in posting which are beyond the advertiser's control. The requirement relating to the risk communication can be met linking to the MedEffect Canada page.

- A direct link to the TMA and the risk communication on the corresponding Canadian gated product website (e.g. www.productnamePM.ca)

- A direct link to the TMA and the risk communication on the Market Authorization Holder's corporate website (e.g. www.companynamePM.ca)

7.3.2b A separate review of the link destination webpage is not required where the contents of that page are limited to the following:

- TMA and risk communications for APS
- Reference list and/or study parameters [s4.4]
- Product logo (without tagline) or the corporate logo
- An optional link to the post-gate homepage when the web link destination is part of a broader site
- An optional footer containing legal elements such as the privacy policy, terms of use, and contact information
- Optional branding colour scheme (but no images)

Web link destination pages having additional content (whether text or images) are required to be submitted for PAAB review as a separate APS.

7.3.2c The content on the destination site must be in the same language as the APS.

7.3.2d The Market Authorization Holder is required to ensure that the link and the destination are maintained for the duration of the preclearance period.

7.3.2e Where mandated by the consumer advertising regulations [s6.5.6], websites housing any content in addition to the TMA and risk communications must be either be gated or de-indexed from search engines (i.e. such that there is no consumer access through search engine results).

If the site is gated, the URL or electronic link promoted in the APS must bypass the gate such that password entry is not required to access these disclosure documents. The URL and electronic link must therefore be promoted only to HCPs.

7.4 Corporate Advertising/Promotion Systems (APS)

These are designed to create and maintain a favorable image of a company, its products and its services. See items exempt from PAAB review [s6.6(v)].

These systems may be used at any time at the discretion of the advertiser but must be submitted for PAAB review and acceptance prior to publication. They must not contain therapeutic or other claims of product merit or status. They may contain:

i) A general statement about the pharmaceutical company, its products and its service(s) and policies.

ii) A partial or complete list or illustration of products manufactured and/ or distributed by the company, along with their respective therapeutic [s11] or pharmacologic [s11] classifications.

7.4(a) PI does not have to accompany corporate advertising.

7.5 Editorial Advertising/Promotion Systems (APS)

Editorial advertisements are used to present company opinions on current issues, and disseminate updated information relative to therapeutic or pharmacologic class areas in which the company has a vested interest. This may include objective, balanced and scientifically rigorous information with discussion of therapeutic aspects of, or research related to, drugs. There is no emphasis on information specifically about the sponsor's product(s). The information on a specific drug is consistent with the current Product Monograph for that drug.

They comprise company-generated open letters, editorials, congress, conference and meeting reports, etc. published as paid advertising. They must be clearly identified as advertising to distinguish them from other editorial presentations.

All such materials must be submitted for PAAB review and clearance prior to distribution to health professionals.

7.5.1 Publication by the company of single-sponsored [s11] editorial reports in compliance with the company's Health Canada authorized product(s) information is acceptable. In addition to identifying the article as advertising, the author(s) should be identified along with any link to the sponsoring company.

The material may make reference to investigational research and must include a disclaimer that a drug has not been authorized for such use in Canada and other pertinent qualifying information. 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.

Healthcare Product branding elements should not be used in non-branded APS that contain statements, visuals, and references that would not be accepted in a product APS.

All copyright regulations must be respected.

8. Clearance Procedure and Operations

8.1 Submission of Material

i) A fee for review of submitted materials is charged in accordance with a schedule published annually. Invoices are rendered after the completion of the initial review. Payment is not contingent on final acceptance of the Advertising/Promotion Systems (APS).

ii) All materials submitted to the PAAB will be confidential unless otherwise stated by the sponsor. Materials for clearance should be clearly marked 'CONFIDENTIAL' to ensure confidentiality of information in submitted copy.

iii) The PAAB will make the final assessment of the category for billing purposes.

8.2 Requirements for Clearance

i) All submitted materials are evaluated by the PAAB, with appropriate consultation, when warranted.

ii) Clearance is conditional upon compliance with all applicable requirements of the PAAB Code of Advertising Acceptance.

8.3 Time Interval for Clearance

i) The maximum time interval for comments on the first review is usually ten (10) business days from date of receipt by the PAAB. The PAAB requires all advertising materials, including copydeck and layout, and necessary supportive information prior to initiating & completing the review.

8.4 Duration of Clearance

i) The maximum effective duration of clearance for advertising containing no price information, price or market-share comparisons, is twelve (12) months. Advertising containing price and/or market share claims must be validated again after six (6) months to maintain clearance.

ii) All advertising scheduled for presentation beyond 12 months must be resubmitted for clearance at least six (6) weeks prior to expiry of the applicable clearance period.

Explanatory Notes section ends here.
The code continues in two columns.

iii) Under special circumstances, e.g. adjustment to a new 12 month advertising schedule or a delay in production of new material, the Commissioner may extend the PAAB clearance beyond the 12-month period. Extensions at no fee charge shall be restricted to no longer than two (2) consecutive months. Longer extensions shall be subject to the full fee applicable to the particular type of advertisement.

8.5 Accepted Advertising

i) The PAAB will provide written notification of acceptance of an APS to the submitting company or agency. PAAB approved APS are allocated an identification code comprising the PAAB Logo, advertisement registration number, type of ad, language(s) and effective 12 month clearance period.

The identification code should be included in all insertion orders for the information of publishers.

ii) The PAAB logo must appear in both the display and PI sections of the advertisements.

8.6 Unaccepted APS

i) Proposed APS requiring revisions

An APS found unacceptable by the PAAB Reviewers, whether on first submission, resubmission after revision, or resubmission after expiry of the effective clearance period, will be returned to the advertiser with a memorandum identifying the questionable points and portions of the APS requiring modification, and an explanation of the basis for the negative ruling.

ii) Clarification of review decisions

Further clarification of the Reviewer's ruling will be provided on request, through correspondence or by telephone. Subject

to availability and workload, Reviewers may agree to requests for meetings with advertisers at the PAAB offices, if it will facilitate the review process. The annual fee schedule may provide for charges to be invoiced for meetings under stated conditions.

Review decisions may be escalated to the Chief Review Officer (CRO) with the following procedure: after having discussed a written review comment with the PAAB Reviewer, responding in writing and receiving a subsequent PAAB letter about the same issue, the sponsor may choose to request a teleconference with the CRO for clarification of the issue.

8.7 Withdrawal of Clearance

i) Conditions for withdrawal of clearance

At any time, the Commissioner may withdraw PAAB clearance and request suspension of publication of an APS on the following grounds: on the basis of a complaint upheld under Section 9; cases where regulatory or independent medical advice suggest that the claims may constitute an imminent and/ or significant health hazard; instruction from the Board; new information coming to light judged significant by the Commissioner; error or omission of fact. To effect the withdrawal of clearance, the Commissioner will write to the advertiser, providing the notification that clearance is withdrawn, along with a rationale for this action. This letter will also contain a schedule setting out by which date use of the material is to cease. This schedule shall be determined by the Commissioner, in consultation with the advertiser, so that the schedule is reasonable with regard to operational concerns.

ii) Advertisers' obligations when clearance withdrawn

If PAAB acceptance of an APS is withdrawn during the effective clearance period, and the ruling is not appealed under Section 9.7.1, the advertiser shall take the necessary action to withdraw the affected APS from publication or other use according to the schedule set by the Commissioner, or if none was detailed, at the earliest feasible date. Before distribution is resumed, the offending APS must be revised and resubmitted for PAAB review, and these changes must be acceptable to the PAAB Commissioner before use.

9. Complaints and Appeals Procedures

9.0 Introduction

This section contains a guide for the resolution of complaints against pharmaceutical advertising that is subject to review by the PAAB. In following these administrative procedures, it should not be necessary for organizations to act through legal counsel. As with all self-regulation, organizations are encouraged to act in the spirit of the Code to seek resolution and abide by those terms, even in specific situations that are not directly anticipated within this section.

9.1 Access to complaint procedure

Complaints against Advertising Promotion Systems (APS) [s11] may be lodged by: health professionals, health care organizations, pharmaceutical companies, federal regulatory bodies including Health Canada and drug payer organizations including provincial ministries of health.

9.2 Complaint letters

9.2.1 Form and content of complaint
Complaints must be in written form. The complaint should set out in a clear manner those

aspects of the APS that are the subject of complaint, referring to the sections of the PAAB Code that the APS is alleged to violate.

9.2.2 Attachments to the complaint

A copy of the APS under dispute should be attached. Articles or other information cited in the complaint also should be attached, unless these sources have been cited as references in an APS reviewed and accepted by the PAAB.

9.2.3 Complaints against APS not reviewed by the PAAB

Complaints may also be lodged against promotional material that does not carry the PAAB logo and appears not to have been accepted by the PAAB. In these cases, complaint letters should first assert that the piece should have been reviewed by the PAAB, and then may complain against subject material of the APS alleged to violate the Code. As soon as the advertiser has been notified of the complaint against an APS that had not been issued a PAAB acceptance, any further use of that APS must cease until the complaint has been reviewed and a ruling issued.

9.3 Signing authority

Complaints must be signed by a senior official [s11] of the complainant organization. If the organization has directed a third party, such as an advertising agency, to prepare a complaint, the senior official must sign to indicate his or her concurrence.

9.4 Complaint resolution Stage 1:

Procedure for complaints from pharmaceutical companies only

9.4.1 Intercompany dialogue

The PAAB wishes to encourage direct communications between the complainant and the advertiser. The complainant company should address the letter of complaint, described in Section 9.2 above, directly to the advertiser, with a copy sent to the PAAB Commissioner.

9.4.2 Advertiser's response

The advertiser shall make written response to the complainant no later than 10 working days after the complaint is received at the advertiser's place of business. A copy of the response should be sent to the PAAB Commissioner. The response shall address each part of the complaint, and indicate whether the advertiser intends to revise the APS or, if not, why the APS does not violate the PAAB Code. Such a response might show, for example, how the contested claims are adequately supported by the references cited in the APS.

9.4.3 Procedure if advertiser not notified

If the complainant does not notify the advertiser but sends a letter of complaint to the PAAB Commissioner, the Commissioner will provide a copy to the advertiser. The 10-day period for response will begin on the date of receipt of this copy at the advertiser's place of business.

9.4.4 Special intercompany dialogue procedures

Companies are encouraged to meet in an attempt to resolve the dispute. If a resolution is found, or an extension to the 10-day response period is needed, the complainant should notify the Commissioner.

9.4.5 Options facing complainant

When the complainant receives a response from the advertiser, the complainant may wish to assess whether to:

(i) continue discussion with the advertiser, possibly by writing another letter narrowing the points of dispute;

(ii) accept the advertiser's response and therefore not pursue the complaint; or

(iii) conclude that further intercompany dialogue will not be productive and therefore seek review by the PAAB Commissioner in Stage 2. The complainant should send a letter of intent to proceed to Stage 2. The letter should be received by the Commissioner within 10 working days of the date of receipt of the advertiser's Stage 1 response by the complainant. The Stage 2 allegations should be clearly stated. Failure to comply with this section will result in the Commissioner voiding the complaint. If the complainant requests action after the ten working day deadline, they may file a new Stage 1 complaint.

9.4.6 Registration of complaints to proceed to Stage 2 resolution

In order for a complaint to pass to Stage 2, the complaint must be registered by sending written confirmation to the PAAB Commissioner that the company wishes to pursue the complaint. A registration fee of $500 will be charged to the complainant company at this time; the fee is refundable if the complaint is found valid.

9.4.7 Procedure if advertiser does not respond

If no response from the advertiser is received by the PAAB or the complainant within 10 working days of the date of receipt of the complaint, the complainant company is entitled to move immediately to request registration of the complaint.

9.4.8 Registration of complaint in exceptional circumstances

The Commissioner is permitted to register a complaint (and proceed to the Stage 2 review) before the 10-day period for advertiser's response has elapsed when regulatory or independent medical advice suggest that the claims may constitute an imminent and/ or significant health hazard. No registration fee will be charged in these cases.

9.5 Complaints resolution Stage 1:

Procedure for complaints other than from pharmaceutical companies

9.5.1 Initiation of complaint

The complainant may address the letter of complaint, described in Section 9.2 above, to the PAAB Commissioner.

9.5.2. Notification of advertiser

The PAAB Commissioner will then send a copy of the complaint letter to a Senior Official [s11] of the advertiser, unless the complainant specifically requests anonymity; in that case the PAAB Commissioner will provide an excerpt of the complaint to the advertiser.

9.5.3 Advertiser's response

The advertiser shall make written response to the PAAB Commissioner no later than 10 working days after receipt of the complaint. The Commissioner will ensure that the complainant receives a copy of the response. The response shall address each part of the complaint, and indicate whether the advertiser intends to revise the APS or, if not, why the APS does not violate the PAAB Code, showing, for example, how the contested claims are adequately supported by the references cited in the APS.

9.5.4 Registration of complaint

In order for a complaint to pass to Stage 2, the complaint must be registered. Under Section 9.5, complainants other than from pharmaceutical companies are not liable to pay registration fees. If the advertiser does not respond by 10 working days after receipt of the complaint, registration is deemed to occur on the subsequent working day. If the advertiser does respond within 10 working days, the complainant may request registration by notifying the Commissioner. The complainant should send a letter of intent to proceed to Stage 2. The letter should be received by the Commissioner within 10 working days of the date of receipt of the advertiser's Stage 1 response by the complainant. The Stage 2 allegations should be clearly stated. Failure to comply with this section will result in the Commissioner voiding the complaint. If the complainant requests action after the ten working day deadline, they may file a new Stage 1 complaint.

9.5.5 Registration of complaint in exceptional circumstances.
The Commissioner is permitted to register a complaint (and proceed to Stage 2 review) before the 10-day period for advertiser's response has elapsed, for example, when regulatory or independent medical advice suggests that the claims may constitute an imminent and/ or significant health hazard.

9.6 Complaints Resolution Stage 2:
Commissioner's reassessment

9.6.1 Commissioner's reassessment
Once a complaint has been registered, the Commissioner will conduct a reassessment of the complaint and may issue rulings.

9.6.2 Scope of the reassessment
In the reassessment, the Commissioner shall examine the letter of complaint and the advertiser's response. The review shall include evaluation of the data supporting promotional claims and if the APS had been previously reviewed, an examination of the way the PAAB Code was applied. The Commissioner may consult with the PAAB Reviewers to request a revised opinion based on additional considerations, or may engage external advice.

9.6.3 Outcomes of the reassessment
The Commissioner will attempt to clarify the issue and narrow down the areas of disagreement. If an agreement between complainant and advertiser is thought to be feasible, the Commissioner may recommend further dialogue, a face-to-face meeting or other conciliation attempts. If none is possible, the Commissioner will issue a ruling, rejecting or accepting all or part of the complaint and as part of this ruling may withdraw clearance for the APS. Also the ruling may address the issue of whether a registration fee under Section 9.4.6 is refundable.

9.6.4 Timelines
The Commissioner's reassessment will be completed within 15 working days, although this period may be extended by two weeks if written notice is given to both companies.

9.7 Complaint Resolution Stage 3:
Review Panel

9.7.1 Right of appeal
This right exists for the use of pharmaceutical industry sponsors of advertising. Either the complainant or advertiser has the right to appeal the Commissioner's reassessment ruling to a Review Panel. Notice of appeal must be provided within 5 working days after the date of the ruling, in a letter to the PAAB Commissioner from a senior official of the organization.

9.7.2 Composition of Review Panel
The appeal will be heard by a Review Panel, comprised of three qualified individuals. The Commissioner will select these three persons from a larger pool of individuals named by national organizations in response to a request from the PAAB; the pool may contain physicians, pharmacists or senior pharmaceutical marketing officials. The Commissioner will request one Panelist to act as Chair. Subject to availability of Panelists, the hearing shall normally be held within 6 weeks of receipt of notice of appeal.

9.7.3 Binding decisions
Decisions by review panels are binding and final.

9.7.4 Objection to selection of Panel members
Each party to the appeal will be given written notice of the identity of the Panelists. Either party may object to the inclusion of an individual Panelist if the objecting party has a reasonable apprehension of bias on the part of such Panelist. Such objection must be registered in writing

to the Commissioner within 2 working days of notice of the Panelists' identity.

9.7.5 Conflict of interest

Each person drawn for service as a Review Panelist will be required to attest that he or she has no conflict of interest in hearing the appeal.

9.7.6 Costs

The party that is unsuccessful at appeal, whether that is the complainant or the advertiser, is liable to pay $5,000 plus actual costs for the review panel and preparation. In the event that the Review Panel decides partially in favour of both companies, the panel shall determine the appropriate sharing of costs between the two companies.

9.7.7 Written submissions

The appellant must assemble its case in writing, along with supporting literature. If this material is extensive, the appellant is encouraged to provide an executive summary of no more than 5 pages in length. This material must be delivered within 15 working days of the Section 9.6 ruling (i.e. 10 days after expiry of the right to appeal) to the Commissioner, who will ensure it is distributed to Panelists and to the other party. The appellant is permitted one extension of 5 working days for the delivery of the written case if notice of the extension is provided to the Commissioner and the other party.

After receipt of the written case, the other party will have 15 working days to prepare a written response and deliver it to the Commissioner, and is permitted one extension of 5 working days for the delivery of the written response if notice of the extension is provided to the Commissioner and the appellant.

If either the written case or the response is longer than 20 pages, including appendices, 5 copies of the complete package should be delivered.

The Commissioner will ensure that the written case and the response are delivered to the panel members and to both parties to the appeal, at least 7 days in advance of the panel hearing.

9.7.8 Oral presentation

The appellant will be called upon to make a brief and concise oral resumé of its case. Then the other party will have an opportunity to respond. A PAAB Reviewer will be permitted to describe the basis for the original ruling. Panel members may then direct questions to any party. The Chair then may permit questions or comments from one party to the other, subject to both sides being given equal opportunity.

The oral presentations are intended to summarize the written arguments. Neither company may employ any new evidence, that is, evidence that was not cited in the written case.

9.7.9 Panel decision

After the oral presentation, the panel will retire for a private discussion before making its decision. The decision will be made by majority vote. The written decision will include a rationale for the decision, as well as a ruling on the status of the APS. The written decision will be sent to both parties within 5 working days of the appeal hearing, by facsimile or other electronic means. Hard copy signed by all Panelists will be delivered to both parties as soon as possible thereafter.

9.7.10 Implementation of panel decision

If the Panel decision is not clear concerning the implementation of the decision on the clearance status of a particular APS, or concerning the schedule for replacing the withdrawn APS discussed in Section 8.7, the Commissioner will write an implementation letter to specify the effect of the panel decision.

9.7.11 Attendance at the hearing

The two parties are asked to limit their representation at the meeting to 3 persons.

9.7.12 Public reporting

The following information on the Review Panel decision may be reported to the Board of Directors and in wider distribution through such vehicles as newsletters: the parties involved, a summary of the major points at issue, and whether the appeal was upheld.

9.7.13 Failure to co-operate with procedure

It is anticipated that Stage 3 Review Panel hearings will be rare, and all companies are expected to co-operate with these procedures. The Commissioner may deem a company to have failed to co-operate with the procedure if, for example, it refuses to prepare a written response or to appear at the hearing, or objects in an unreasonable manner to the selection of panelists. If the company fails to co-operate and, in the opinion of the Commissioner, is likely to gain a material commercial benefit from this failure to co-operate, the Commissioner is authorized to proceed with the Review Panel hearing and decision without that company's co-operation. In such a case, the Commissioner is directed to ensure a high degree of fairness in the processes of the Review Panel, in the selection of Panelists, and presentation of written and oral material before the Panel.

9.7.14 Modifications to Review Panel procedure if complainant is not a pharmaceutical company

Certain procedures in Section 9 will be modified when the complainant is not a pharmaceutical company:

i) These complainants are not liable to pay Costs in Section 9.7.6

ii) If the advertiser has taken the issue to appeal, (because the advertiser lost the Stage 2 Commissioner's reassessment), and the complainant does not wish to play an active role at the Review Panel stage, the Commissioner will take steps to ensure that the complainants' case is brought forward for assessment by the Review Panel, including the preparation and submission of a written response based largely on the initial complaint, and presentation of an oral submission.

iii) If the complainant has taken the issue to appeal, and in the opinion of the Commissioner the questions at issue are principally policy issues that should be brought to the attention of the Board of Directors, the Commissioner is authorized to send the issues to the Board of Directors for discussion rather than to invoke the Review Panel procedure in Section 9.7. After this discussion, the Board of Directors would authorize a response to the complainant. The referral to the Board of Directors is appropriate when the questions at issue, in the opinion of the Commissioner, relate more to the complainants' views as to how the PAAB Code should be written rather than matters of fact or interpretation of the existing Code.

9.8 Appeals of negative PAAB clearance rulings for a proposed APS

9.8.1 Right of appeal

Apart from appeals relating to third-party complaints which are defined in Sections 9.1 to 9.7, an advertiser who has submitted a proposed APS has the right to appeal a negative PAAB clearance ruling, on first submission or resubmission.

9.8.2 Discussion with Commissioner

Advertisers are encouraged to discuss their differences first with the Commissioner. The advertiser may request that the Commissioner review the file, and the Commissioner may confirm or revise the PAAB's negative clearance ruling.

9.8.3 Appeal to Review Panel

If not resolved in Section 9.8.2 and if the company wishes to appeal an issue further, a written notice of appeal must be signed by a senior official of the appellant organization asking that the matter be heard by a Review Panel.

9.8.4 Procedure for Review Panel

The Commissioner will ask the PAAB chair to convene a panel of 3 PAAB directors to hear the complaint and make a decision. A decision shall be sought within 30 days. If the appeal is unsuccessful, the appellant company is liable to pay $5,000 plus actual costs.

9.9 Penalties, remedial measures, and public reporting of complaints

9.9.1 Appropriate penalties

In rulings on complaints and in the implementation of Panel Decisions, the Commissioner may set out penalties against companies for Code violations. The appropriate penalty will be selected in accordance with the degree of the Code violation. Examples of penalties could range from immediate withdrawal of offending advertising, to notices in annual reports or newsletters, to public letters of apology. The Board of Directors may develop a Guideline on Penalties that outlines for the Commissioner's use a hierarchy of appropriate penalties, including penalties other than those mentioned above, with sanctions of increasing severity for serious or repeated violations. The commissioner may inform the appropriate trade association to assess the complaint ruling for further penalties if warranted.

9.9.2 Remedial measures

When material has been disseminated that is substantially misleading, or where the information may cause inappropriate product use or constitutes an imminent and/ or significant health hazard, the Commissioner may require remedial measures contained in letters of correction or published notices. Content and form of these remedial measures must be approved by the Commissioner. The remedial measures should be distributed to the original target audience using the same or similar media [s11], and must be implemented within 30 days of the Commissioner's instruction.

9.9.3 Public reporting

The Commissioner is authorized to make public reports of notable Code violations in vehicles such as annual reports, and newsletters. These reports may include identification of the advertiser, the method of distribution, whether the information was submitted for PAAB review, the reason why the information was found to violate the Code, penalties required and any other relevant information. Particular attention is to be given to repeat offenses, and to advertisers which refuse to comply with a Commissioner's ruling or Review Panel decision.

9.9.4 Reporting to Board members

The Commissioner also will make annual summary reports of complaints and their disposition to Board members, including ex-officio members representing regulators.

9.9.5 Health Canada

Where complaints have been brought to the PAAB for resolution, and the advertiser has not complied with rulings by the Commissioner or a Review Panel, the Commissioner shall inform Health Canada to request an investigation within the requirements of the Food and Drugs Act. The Commissioner is also expected to bring to the attention of Health Canada advertising believed to present an imminent or significant health hazard. Detailed procedures are described in the current Health Canada document, setting out the PAAB and Health Canada roles and consultation related to advertising review.

10. Monitoring Program

Explanatory Notes

The Board invites the full cooperation and participation of all advertisers, agencies, media [s11] and health professionals in monitoring the various aspects of the PAAB program.

10.1 Advertising/ Promotion Systems (APS)

i) The PAAB monitors all APS to determine whether they have received PAAB clearance.

ii) Any company whose APS has been published without PAAB clearance is contacted immediately by the PAAB and requested to suspend further distribution of the APS until it has received PAAB clearance. The PAAB will send a copy of this letter to the publishers or their agents.

iii) If a PAAB-accepted APS does not bear the PAAB logo the PAAB will contact the advertiser and request that the logo be inserted at the earliest opportunity.

10.1(ii)a Penalties for violations will be dealt with under Sections 9.9 of the Code.

11. Definitions

Definitions are in alphabetical order.

Advertising or Promotion

For purposes of this Code, advertising or promotion or advertising/ promotion system (APS) is defined as any paid message communicated by Canadian media, with the intent to influence the choice, opinion or behavior of those addressed by commercial messages. This definition applies even if the information: a) has been published independently of the manufacturer e.g. clinical reprints, meeting reports; b) is from an independent authoritative source; c) is unchanged and complete; d) is claimed to be educational material. Distribution of any unsolicited material about a pharmaceutical product is deemed to be advertising if the information or its distribution serves to promote the sale of that product, either directly or indirectly.

Applications (app)

Apps are programs that typically run on Smartphones and are accessed either through download or through the App Store for the user's platform. When the App Store includes reviews of the app products, Pharma should ensure that wording of reviews fall within the restrictions of Canadian regulations.

Clinical Relevance

Refers to the practical value of the claim itself in assisting prescribers and consumers to select an appropriate therapy and to the practical value of a statistically significant effect when one treatment is compared to another.

Coding System

The abbreviated computer codes created to transmit messages in brevity or secrecy (e.g., QR codes).

Comparative Claim

A statement that compares an identified attribute of one drug product/ ingredient to that of another drug product(s)/ ingredient(s) in terms of comparability or superiority.

Conditions of Use

The circumstances, under which the product is used for the authorized indication, e.g. with adjunctive therapies, in-patient vs. outpatient, daytime vs. nighttime use.

Consumer

Members of the general public.

Continuing Education (CE) Event or Health Professional Meeting

A group learning activity such as a course, conference, congress, symposium, workshop, seminar or meeting, sponsored by an accredited CME provider e.g. medical school CME offices, Royal College accredited National Specialty Societies, the national and provincial chapter offices of the College of Family Physicians of Canada (CFPC), Fédération des médecins omnipraticiens du Québec (FMOQ), Fédération des médecins spécialistes du Québec (FMSQ) and the Canadian Council for Continuing Education in Pharmacy (CCCEP). Rounds are not considered to be Health Professional Meetings in the context of Meeting Reports.

Current Data

1. Published or unpublished clinical or laboratory studies which have not been superseded by more recent and relevant data and information.
2. Market research data valid at the time of submission of the Advertising/Promotion System.

Drug Identification Number (DIN)

The 8-digit number located on the label of prescription and over-the-counter drug products that have been evaluated by Health Canada and approved for sale in Canada.

Established Healthcare Product

Any prescription, non-prescription or Natural Health Product manufactured and/ or marketed in Canada for 2 years or longer.

Fair balance

Refers to the presentation of accurate and fair assessment of the risks as well as the benefits of the drug. Fair balance is achieved when the overall presentation of information in the APS does not convey a deceptive impression of the drug's risk or benefits.

Healthcare Product

A substance or mixture of substances manufactured, sold or represented by a specific manufacturer for in vivo use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof; or in restoring, correcting or modifying function(s) in humans. This includes: drugs listed on all schedules of the Food & Drugs Act and Regulations that have a Drug Identification Number (DIN) assigned by Health Canada; and Natural Health Products that includes traditional herbal medicines; traditional Chinese, Ayurvedic (East Indian) and Native North American medicine; homeopathic preparations; and vitamin and mineral supplements that have a Health Canada assigned NPN or DIN-HM and "pharmaceutical products".

This **excludes** medical devices and cosmetics* as defined in the Food and Drugs Act and Regulations; products used for in vitro diagnosis of conditions, both normal (pregnancy test kits) or in connection with disordered states of health (blood glucose monitoring devices for diabetes, contact lens solutions, etc.); and food and vitamins being promoted purely for the maintenance of normal health.

*Therapeutic cosmetics, e.g. medicated and hypoallergenic preparations, are classed as pharmaceutical products. Advertising/ Promotion Systems (APS) for such products must be submitted for PAAB review and clearance.

Healthcare Professional (HCP)

Licensed members of the professions of medicine, dentistry, naturopathy, homeopathy, nursing, pharmacy and other related disciplines.

Indication(s) For Use

Is (are) the therapeutic/diagnostic/prophylactic use(s) defined in the authorized product information, and may include limitations to the drug product's use, such as the applicability to a specific population e.g. pediatric, or other special conditions e.g. in combination with other therapies.

Ingredient

Refers to the active ingredient(s) unless otherwise qualified.

Linking

Providing the ability to display or activate another document or website from a point on the current document or website.

Marketing benefit claim

A statement that is designed to promote the sale of a health product. It often highlights a specific product attribute i.e. "longer lasting" or "tastes great".

A promotional statement designed to inform about the product's availability and benefits so as to form/ alter the audience's opinion of the medication. It can be explicit (i.e. text) or implicit (i.e. images), comparative or non-comparative. It can relate to pharmacological or non-pharmacological properties of the product.

Not all statements about a product are "marketing claims of benefit". Common examples of product messaging which are not considered marketing benefit claims include product reconstitution instructions, monitoring instructions, dosing modifications for special populations and storage instructions when these are presented as instructions/ burdens rather than features/ benefits (i.e. presented to instruct rather than alter/ form the audience's opinion of the medication in a positive way). How a statement is framed can sometimes affect whether it is a marketing benefit claim. For example, the copy "Arbace: Convenience of a single daily dose" is a marketing benefit claim, while "Patients should be instructed to take a single dose daily at the same time each day" is not.

Media

Encompasses all means of distribution of Advertising/Promotion Systems (APS) to the health professions.

Natural Health Products (NHP)

Naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.

Natural Product Number (NPN)

Identifies that a natural health product has been licensed.

New Healthcare Product

Any prescription or non-prescription product manufactured and/ or marketed in Canada by a particular company for a period of less than 2 years. Use of the word 'new' or statements implying "new" in advertising should be restricted to 1 year after initial marketing.

Observational study

An observational study draws inferences about the possible effect of a treatment on subjects, where the assignment of subjects into a treated group versus a control group is outside the control of the investigator. This is in contrast with experiments, such as randomized controlled trials, where each subject is randomly assigned to a treated group or a control group before the start of the treatment.

Patient

A person who has been prescribed a drug product by a health care professional.

Pharmacologic Classification

Identifies the pharmacologic action of the healthcare product (anxiolytic, diuretic, antibiotic, analgesic etc).

Prescribing information (PI)

Includes important information that may be required for the optimal, safe and effective use of a drug product, such as mechanism of action; indications and contraindications for use; and dosage instructions. For example, for healthcare products having a Product Monograph, the information provided in Part I of that monograph constitutes prescribing information.

PAAB considers a link to the Terms of Market Authorization for any product (whether prescription or non-prescription) to satisfy this code's requirement for a link to "prescribing information".

Product Claim

A claim related to general merit, quality of life, economics, market position or status, or comparative advantage.

Rational Drug Therapy

Appropriate therapy, recommended or prescribed, that may be expected to remedy or ameliorate a disordered state of physical or mental health or that may be employed for diagnosis and prophylactic purposes to prevent or lower the incidence of illness.

Really Simple Syndication (RSS)

A simple XML schema that allows readers to pull data and display it any way they choose. Used for blogs and press releases to expand the ways people can access the information.

Risk Communications

Risk communications are used as part of any risk management program. For the purpose of this code, "risk communications" refers to communications issued by (or in collaboration with) Health Canada to convey new or emerging health product safety information about the promoted product. For more information, please refer to the Health Canada guidance document "Description of Current Risk Communication Documents for Marketed Health Products for Human Use".

Search Engine Marketing (SEM)

A form of Internet marketing that involves the promotion of websites by increasing their visibility in search engine results pages through optimization (both on-page and off-page) as well as through advertising (paid placements, contextual advertising, and paid inclusions).

Search Engine Optimization (SEO)

The process of improving the visibility of a website or a web page in a search engines' "natural" or un-paid ("organic" or "algorithmic") search results.

Senior Official

A person fulfilling one or more of the following functions in an organization: Chief Executive Officer, Vice President, Head or Director of Marketing, Medical or Regulatory.

Single Sponsor

Any commissioned communication prepared or controlled by the manufacturer or its agent such as journals, newsletters and other publications.

Social Media

The broad term for internet activities that engage or encourage engagement through online discussions or interactions. E.g.: blogs (personal online journal comprised of entries/posts), microblogs (Twitter), chat rooms, forums, video/photo sharing (YouTube, Flickr), social networking (Facebook), podcasts, user forums/discussion groups, wikis (website where content is added, modified or deleted by the users), news aggregation (RSS), apps etc.

Terms of Market Authorization (TMA)

Information in the Product Monograph, labeling and product license and the document that assigns a Drug Identification Number (DIN), Natural Health Product number (NPN) or homeopathic product number (DIN-HM), including related product labeling material and prescribing information, authorized by Health Canada.

Therapeutic Claim

A claim of effectiveness and/or safety of a healthcare product for the purpose(s) intended.

Therapeutic Classification

Identifies the condition(s) of therapeutic use of the healthcare product e.g. migraine, hypertension, peptic ulcer, psoriasis, etc.

User-generated Content (UGC)

Any material that is created by and posted by, a user. Examples of user-generated content are: a "like" rating on an article, a Link rated and forwarded, a comment added into an open text field, a descriptor selected from a list of choices, a photo or other media uploaded.

Uniform Resource Locator (URL)

The "human-friendly" addresses of resources on the Internet. An example is: www.PAAB.ca.

Web Link Destination

The webpage produced by clicking a provided electronic link or by entering a provided URL into the browser address bar.