Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada

Canadian Generic Pharmaceutical Association (CGPA)

Effective April 1, 2019

TABLE OF CONTENTS

Date Adopted:	**January 1, 2019**
Effective:	**April 1, 2019**
Supersedes:	**August 21, 2013**

CODE OF MARKETING CONDUCT GOVERNING THE SALE OF GENERIC PHARMACEUTICAL PRODUCTS IN CANADA

1. INTRODUCTION

CGPA

The Canadian Generic Pharmaceutical Association ("CGPA") is the trade association representing Canada's manufacturers and distributors of finished Generic Pharmaceutical Products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.

The members of CGPA are committed to operate in a professional, ethical and transparent manner to ensure the appropriate use of medicines by patients and support the supply of quality and affordable Generic Pharmaceutical Products (Capitalized terms have the meanings ascribed thereto in section 2 herein or as otherwise defined in this Code).

Code of Marketing Conduct

This Code of Marketing Conduct (the "Code") is principle based, providing guidance on the different applicable laws, regulations and standards to which Manufacturers of Generic Pharmaceutical Products adhere.

The purpose of this Code is to:

- Formalize the commitment of Manufacturers of Generic Pharmaceutical Products in Canada to guidelines compliant with applicable laws, regulations and standards that encompass best practices, self-regulation with respect to the supply of Generic Pharmaceutical Products in Canada;

- Ensure that generic pharmaceutical manufacturers and distributors operate in a responsible, ethical and professional manner through a self-regulated approach;

- Identify the unique objectives of the generic industry sector in its relationships with Customers, Healthcare Professionals and Government, and provide guidance as to how this relationship can be developed in a way consistent with appropriate and applicable industry, professional and ethical standards; and

- Assist Manufacturers to promote and maintain a culture of responsible supply of Generic Pharmaceutical Products.

Although the industry has a legitimate right to encourage the use of Generic Pharmaceutical Products to Customers, Healthcare Professionals and to the Government, this Code recognizes, and seeks to achieve, a balance between the needs of patients, Healthcare Professionals and the General Public, bearing in mind the legislative, regulatory, political and social environment within which the industry operates and the statutory controls governing the commercialization of Generic Pharmaceutical Products.

Scope

This Code applies to all activities of CGPA members, their Representatives, and other third parties acting on Manufacturers' behalf, for the purpose of encouraging the use of a Generic Pharmaceutical Product anywhere in Canada. This Code does not apply to the promotion and sale of biosimilars, raw material, non-prescription products, natural health products or medical devices.

Although this Code has no authority over non-members of CGPA, all such generic pharmaceutical manufacturers are encouraged to adhere to the principles outlined in this Code on a voluntary basis. In certain provinces, adherence to this Code may be mandatory in order for a manufacturer to get its products listed on the public drug insurance program formulary.

Non-members of CGPA who decide to voluntarily comply with this Code may provide a declaration of compliance with this Code to CGPA.

Enforcement

Complaints under this Code are considered by an arbitrator appointed by the President of CGPA or its delegate, following the procedure established by this Code. Reports on substantiated complaints are published by the CGPA in its annual report and on its website, as specified in section 15.7.3.

Contact and Allegation of Breach

Any allegation of breach of this Code by a Manufacturer or questions regarding this document or about generic pharmaceutical products in general should be directed to:

Canadian Generic Pharmaceutical Association
4100 Yonge Street, Suite 501, Toronto, ON, M2P 2B5
Tel: 416-223-2333 Fax: 416-223-2425
Website: www.canadiangenerics.ca E-mail: info@canadiangenerics.ca

2. DEFINITIONS

In this Code, the following terms and expressions have the following meanings:

"**Generic Pharmaceutical Product(s)**" means, for the purpose of this Code, a prescription pharmaceutical product that has been proven to be pharmaceutically equivalent to an approved reference pharmaceutical product in terms of dosage, strength, route of administration, performance, and intended use, but excluding biosimilars, raw material, non-prescription products, natural health products or medical devices.

"**Manufacturer(s)**" means the Members of CGPA and all other manufacturers, suppliers or distributors of Generic Pharmaceutical Products that apply this Code on a voluntary basis.

"**Customer(s)**" means any purchaser, potential purchaser, intermediary, or other party that may influence directly or indirectly the purchasing of a Manufacturer's Generic Pharmaceutical Products, including group purchasing organizations, wholesalers, operators of pharmacies, companies or persons (including pharmacists) that own, operate or franchise pharmacies, and their respective directors, officers, employees and agents. Customer may refer to a Healthcare Professional or Government. In such situation, this Code must be interpreted with applicable adaptations.

"**General Public**" means the general population of Canada, except for Healthcare Professionals, Patients, and individuals working in, or who are knowledgeable of the pharmaceutical industry and of pharmaceutical products.

"**Government**" means any federal or provincial government departments, Crown corporations or companies owned or partially owned by the federal or a provincial government, and public institutions (including, for clarity, public healthcare facilities and health authorities).

"**Healthcare Professional(s)**" means any person who by education, training, certification, or licensure is qualified to and is engaged in providing health care services to patients, such as physicians, dentists, nurses, pharmacists, and any other person working for, or assisting such person in its professional practice.

"**Patient(s)**" any person to whom a Generic Pharmaceutical Product (or a product for which such Generic Pharmaceutical Product is interchangeable) has been prescribed.

"**Representative(s)**" means any person interacting with Customers and/or Healthcare Professionals on the Manufacturer's behalf, including employees.

3. GENERAL PRINCIPLES

Appropriate interactions for the marketing and sale of Generic Pharmaceutical Products ensure that patients have access to these products that they need and that the products are used correctly for optimal Patient benefit. In conducting their business, the Members of CGPA and other complying Manufacturers agree to apply those following principles:

1- Support the long-term sustainability of healthcare budgets by ensuring the timely and cost-effective provision of quality Generic Pharmaceutical Products for all Canadians;

2- Encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate use and interchangeability of Generic Pharmaceutical Products amongst Healthcare Professionals, Government and the General Public by the provision of accurate and fair information;

3- Re-enforce the accountability of Manufacturers by establishing a complaint handling mechanism with respect to the commercialization of Generic Pharmaceutical Products that is both readily accessible and transparent; and

4- Ensure that interactions with Customers, Healthcare Professionals, Government and the General Public are conducted in accordance with all applicable laws and regulations, applicable standards and this Code.

4. ADVERTISING AND INFORMATIONAL MATERIAL

4.1. All advertising and informational material disseminated by a Manufacturer to members of the General Public, Healthcare Professionals, Government and Customers, either directly or indirectly, must not contain inaccurate, deceptive or otherwise misleading claims, statements, illustrations or representations, and must not omit relevant information in a manner that is deceptive.

4.2. A Generic Pharmaceutical Product must not be advertised prior to the grant of the Notice of Compliance by Health Canada.

4.3. All advertising must also comply with the *Food and Drug Act*, and all other applicable laws, regulations and industry codes.

5. SCHOLARSHIPS AND BURSARIES

5.1. Financial assistance for scholarships or other educational funds to students and Healthcare Professionals in training may be offered, so long as the selection of individuals who will receive the funds is made by the academic or training institution. Manufacturers will obtain receipt and evidence of appropriate expenditure of such payments by the recipients or the academic or training institution. For clarity, the foregoing does not apply to donations or grants made by Manufacturers to charitable organizations that award scholarships or other educational funds to recipients in accordance with their mandate.

5.2. Nothing should be offered or provided in a manner or on conditions that would bring the generic pharmaceutical industry into disrepute or reduce public confidence in the industry, or constitute an inducement to influence the present or future professional practice of recipients.

6. ALLOWANCES AND REBATES

6.1. Any allowances or rebates granted, directly or indirectly, to a Healthcare Professional or to a Customer must be fully in accordance with any applicable laws and regulations.

6.2. No good or service, or discount on a good or service, may be provided by a Manufacturer to a Healthcare Professional or a Customer as a reduction on the purchase price of the Generic Pharmaceutical Products. If a good or service is provided to a Healthcare Professional or a Customer, the Manufacturer providing such good or service, will ensure that the consideration is consistent with the fair market value for such good or service.

6.3. A Manufacturer must not grant to a Customer any allowances or rebates, if it knows the Customer is going to use such allowance or rebate in a manner that is prohibited by applicable laws and regulations.

6.4. The Manufacturers shall not give or offer, directly or indirectly, any payments or inducements that are either unlawful or improper to any Healthcare Professional or Customer, or that would interfere with a Healthcare Professional’s independence, as required by its professional organization.

7. SAMPLES AND FREE GENERIC PHARMACEUTICAL PRODUCTS

7.1. Subject to sections 7.2, 7.3 and 7.4, the provision of samples and free Generic Pharmaceutical Products to Customers and to Healthcare Professionals is prohibited

7.2. Replacement of expired Generic Pharmaceutical Products may be provided at no cost if the replacement is on a one-for-one unit basis and/or of equivalent value to the expired Generic Pharmaceutical Product and is in accordance with industry norms.

7.3. Generic Pharmaceutical Products may be provided at no cost for humanitarian purposes, when allowed by applicable laws and regulations.

7.4. Even though the provision of samples to Healthcare Professionals is prohibited, the provision of samples to physicians is allowed, as long as it is being done in accordance with all applicable laws and regulations, and that it is in the best interest of patients.

8. GIFTS

8.1. Gifts or any items of material value provided, directly or indirectly, to a Healthcare Professional or to a Customer are prohibited, except as otherwise allowed under this Code.

8.2. A gift or an item of material value can occasionally be provided to a Healthcare Professional or to a Customer, provided it is modest in nature and expense and it doesn't interfere with a Healthcare Professional's independence and it is in accordance with all applicable laws and regulations.

8.3. Appropriate records of any such gifts should be maintained by each Manufacturer providing such gifts or items of material value.

9. MEALS, ENTERTAINMENT AND RECREATION

9.1. Interactions of Manufacturers with Customers and Healthcare Professionals must always be professional in nature.

9.2. Modest, occasional meals, entertainment and recreation are permitted as long as they are offered in connection with business meetings or events that are held for educational, scientific, research or promotional purposes. Offering hospitality must not interfere with a Healthcare Professional's independence and must be in accordance with all applicable laws and regulations.

9.3. The selection of venues for such interactions organized by a Manufacturer must be appropriate and conducive for the business meeting or events. It must not must not

interfere with a Healthcare Professional's independence and must be in accordance with all applicable laws and regulations

10. CONTINUED EDUCATION PROGRAM

10.1. "Continued Education Program" means any education focused event providing current and relevant medical and/or scientific information to prescribing or dispensing Healthcare Professionals that is supported, either financially or administratively by a Manufacturer. Reasonable travel and accommodation expenses can be paid by Manufacturers to Healthcare Professionals for attending a Continued Education Program. The Manufacturer must not pay for travel expenses of anyone travelling with the Healthcare Professional.

10.2. The Manufacturer must not, under any circumstance, provide remuneration to a Healthcare Professional to attend a Continued Education Program.

10.3. Where appropriate, Manufacturers may retain the services of a Healthcare Professional as a speaker or as a moderator for the Continued Education Program and/or seek Continuing Education Program accreditation of events by appropriate provincial and national professional bodies. The choice of the Healthcare Professional should be made based on defined criteria such as general expertise, reputation, communication skills, knowledge and experience regarding a therapeutic product or area. Reasonable travel, accommodation and out-of-pocket expenses, where warranted, and in line with this Code, may be reimbursed. A written contract must be in place between the Manufacturer and the Healthcare Professional, specifying the nature of the interaction between the Manufacturer and the Healthcare Professional. It is appropriate for a Healthcare Professional who provides acts as a speaker or a moderator to be offered compensation that is consistent with the fair market value for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services.

10.4. The venue and circumstances of any Continued Education Program must be conducive to the purpose of the meeting.

11. CONSULTANTS/ADVISORY BOARDS

11.1. Where appropriate, Manufacturers may retain the services of Healthcare Professionals as consultants to advise them on product or on a therapeutic area. The choice of the Healthcare Professional should be made based on defined criteria such as general expertise, reputation, communication skills, knowledge and experience regarding a therapeutic product or area.

11.2. A legitimate need for the consulting services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective Healthcare Professionals.

11.3. The number of Healthcare Professionals retained must not be greater than the number reasonably necessary to achieve the identified purpose.

11.4. The retaining Manufacturer must maintain records concerning, and make appropriate use, of the services provided by Healthcare Professionals.

11.5. The venue and circumstances of any meeting must be conducive to the purpose of the meeting, and discussions with consultants must be the primary focus of the meeting.

11.6. In order to explicitly ensure that there is no conflict between the duties of the retained Healthcare Professional by the Manufacturer, and the other professional obligations of such Healthcare Professional, a written contract must be in place between the Manufacturer and the Healthcare Professional. This contract will specify the nature of the interaction between the Manufacturer and the Healthcare Professional. It is appropriate for a Healthcare Professional who provides consulting or advisory services to be offered compensation that is consistent with the fair market value for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services.

12. ADVERTISING OR BRAND PROMOTION PROGRAMS

12.1. Where applicable laws and regulations allow, a Manufacturer may enter into agreements with Customers for the purpose of advertising or brand promotion programs.

12.2. A written contract must be in place between the Manufacturer and the Customer. This contract must specify the nature of the interaction between the Manufacturer and the Customer. It is appropriate for the Customer to be offered compensation that is consistent with the fair market value for such services.

13. SPONSORSHIP OF EVENTS

13.1. Where applicable laws and regulations allow, a Manufacturer may sponsor an event involving the participation of Customers, such as conventions and tradeshows, on the condition that the sponsorship amount provided is for visibility and the services offered as part of the sponsorship are consistent with fair market value.

13.2. Notwithstanding the above, a Manufacturer may provide financial support/ funding to a charitable event organized in collaboration with a Customer, including by the purchase of visibility, of a table, or of participation to a social/ sporting event.

14. TRAINING OF REPRESENTATIVES

14.1. The Manufacturer’s Representatives must always act with the highest degree of professionalism and integrity when interacting with Customers and Healthcare Professionals.

14.2. Manufacturers should ensure that all Representatives who are acting on their behalf, and who have interactions with Healthcare Professionals and Customers receive periodic training on this Code, and about applicable laws and regulations.

14.3. Manufacturers should also assess their Representatives periodically to ensure that they comply with relevant Manufacturer's policies and standards of conduct, and this Code. Companies should take appropriate action when Representatives fail to comply.

14.4. Each Manufacturer must have an employee or agent responsible for overseeing compliance with this Code, including training requirements.

15. ENFORCEMENT

15.1. Enforcement

15.1.1. The enforcement of this Code is the responsibility of CGPA and of the arbitrator appointed by CGPA, which has the authority to assess penalties for breaches of this Code.

15.1.2. The Allegation handling procedure set out in this Code is intended to be in addition to the other rights of a member of the General Public, Healthcare Professional or Government under applicable laws and regulations, and is not intended in any way to restrict a member of the General Public, a Healthcare Professional or Government from referring the complaint to any other tribunal or agency or other complaints handling body with jurisdiction over Manufacturers, which may be established or in existence from time to time.

15.2. Allegation of breach

15.2.1. The filing of an Allegation of a breach of this Code by a Manufacturer ("Allegation") is free of charge when made by members of the General Public (including consumers or patients associations), Healthcare Professionals, or Government representatives. Representatives from the pharmaceutical industry filing an Allegation must pay a filing fee of $5,000 to cover the costs associated with the administration of the Allegation.

15.2.2. An Allegation must be made in writing to CGPA and signed by the complainant or his or her duly authorized representative (the "Complainant").

15.2.3. The Allegation must include the following elements:

i) the identity of the Manufacturer alleged to have breached this Code (the "Respondent");

ii) the nature of the alleged breach;

iii) the date and place where the alleged breach was allegedly committed; and

iv) the name of the Complainant, his contact details and details of affiliation with any relevant professional, industry or consumer association.

15.2.4. The Allegation must be tabled within 90 days of the alleged breach or of the date when the alleged breach became known to or reasonably ought to have been known to, the Complainant, but no longer than 2 years following the alleged breach.

15.2.5. The identity of the Complainant shall remain confidential and shall at no time be communicated to the Respondent or to its representatives.

15.2.6. On receipt of an Allegation from a Complainant, the President of CGPA or delegate shall acknowledge the complaint in writing within ten (10) business days of receipt.

15.3. **Investigation**

15.3.1. The President of CGPA or delegate shall appoint an independent investigator ("Investigator") within thirty (30) days of receipt of the Allegation.

15.3.2. Within the framework of the investigation, the Investigator may:

i) summarily reject the Allegation received if he/she deems that elements raised do not, on the surface, make it possible to determine whether or not this Code has been breached, or if the Complaint is found to be frivolous, vexatious, or otherwise filed for an improper purpose;

ii) question the Complainant or the Respondent on all facts or proof relating to the Allegation;

iii) question, upon authorization of the Complainant and the Respondent, any other party, including Customer(s) or Healthcare Professional(s) related to the Allegation; and

iv) request from the Complainant and the Respondent the transmission of all documents or elements of proof deemed necessary within the framework of the investigation that are relevant to the Allegation.

15.3.3. The Respondent is expected to cooperate with the Investigator, subject to sanctions.

15.3.4. The investigative process shall be conducted under the supervision of the President of CGPA, to which the Investigator is required to issue a report on the steps followed.

15.3.5. The investigation shall end no later than sixty (60) days following the appointment of the Investigator.

15.3.6. The Complainant has the right to withdraw the Allegation at any time before the end of the investigation. Fees lodged for filing of the Allegation are not reimbursable.

15.4. **Complaint**

15.4.1. Within ten (10) days of the end of the investigation, if the Investigator considers that the elements gathered are sufficient to establish that this Code has been breached, a complaint shall be filed with CGPA (the "CMC Complaint"). Otherwise, a rejection notice shall be issued.

15.4.2. The CMC Complaint or rejection notice must be in writing.

15.4.3. The CMC Complaint must include the following elements:

i) the identity of the Respondent;

ii) the nature of the alleged breach;
iii) the date and place of the alleged breach; and
iv) the disclosure of all facts provided in support of establishing the alleged breach.

15.4.4. The rejection notice must include the reasons for the Allegation's rejection.

15.4.5. The CMC Complaint or notice of rejection shall be communicated, upon receipt, to the Complainant and Respondent by the CGPA.

15.4.6. All information pertaining to the Allegation and to the CMC Complaint is required to be kept confidential by the parties subject to this Code a decision to the effect that the Allegation is substantiated is rendered.

15.5. **Hearing**

15.5.1. Within ten (10) days of the receipt of the CMC Complaint by CGPA, the President of CGPA or it delegate shall appoint an independent, outside arbitrator ("Arbitrator") to rule on its validity.

15.5.2. Although the Arbitrator is not required to conduct a full evidentiary review into the Complaint, principles of natural justice and procedural fairness shall be respected. Subject thereto, the Arbitrator shall have the right to govern its own procedure, and CGPA may adopt written rules of procedure to be followed by the Arbitrator in the course of reviewing any Complaint.

15.6. **Decision**

15.6.1. The Arbitrator shall render a reasoned decision within thirty (30) days of receipt of the Complaint. The decision shall be final and not subject to appeal, unless overturned by a supermajority (at least 2/3) of the members of the Executive Committee of CGPA.

15.6.2. The decision shall be communicated to the Complainant, the Investigator and the Respondent.

15.6.3. The contents of the decision rendered shall remain confidential if the Allegation was found to be not substantiated.

15.6.4. When a CMC Complaint is deemed to be unsubstantiated, the Complainant shall assume costs of the proceeding, except in cases where the Complainant is a member of the General Public (including consumers or patients associations), a Healthcare Professional, or a Government representative.

15.6.5. When a Complaint is found to be substantiated, the Respondent shall assume costs.

15.7. **Sanctions**

15.7.1. Where the Arbitrator finds that a Respondent has breached this Code, the Arbitrator may apply one or more of the following sanctions.

i) A requirement that the Respondent take immediate action to discontinue or modify any practice that is determined to constitute a breach of this Code, in which event the Respondent must confirm in writing to the Arbitrator that it has taken the required action within fifteen (15) business days of receipt of the decision.

ii) A requirement that the Respondent recall and destroy any offending material in which event the Respondent must confirm in writing to the Arbitrator, within fifteen (15) business days of receipt of the decision, that it has taken the required action, or taken steps to initiate the required action which are reasonably satisfactory to Arbitrator.

iii) A requirement that the Respondent issue a retraction, including corrective letters and advertising. The Respondent must confirm in writing to the Arbitrator, within fifteen (15) business days of receipt of the decision, that it has taken the required action and must provide a copy of the retraction once published.

iv) A requirement that Representatives, employees, contractors of agents of the Respondent undertake a course of study or further training on their obligations under this Code, applicable laws and regulations, guidelines or codes. The Arbitrator is to set a timeframe for the completion of any such course of study or further training.

v) The imposition by the Arbitrator of a financial sanction in accordance with the following schedule. The Respondent must pay the financial sanction to CGPA within thirty (30) business days of being advised of the decision of the Arbitrator.

For Minor Breach (no consumer safety implications and no adverse effect on how Healthcare Professionals or the General Public view the safety of the Generic Pharmaceutical Products or industry): $10 000 per offence or related series of offences

Moderate Breach (no safety implications but which have the potential to adversely impact the perceptions of Healthcare Professionals or the General Public regarding the Generic Pharmaceutical Products or industry): Maximum $25,000 per offence or related series of offences

Severe Breach (safety implications or will have a major adverse impact on how Healthcare Professionals or the General Public view the Generic Pharmaceutical Products or industry: Maximum $75,000 per offence or related series of offences

Repeat Breach (same as or similar to a breach found against the same Respondent within the preceding twelve (12) months): Maximum $100,000 per offence or related series of offences

vi) A recommendation to the CGPA Board of Directors to terminate the membership of the Respondent from CGPA.

15.7.2. In the event that the Arbitrator requires a Respondent to cease conduct or withdraw an activity and the Respondent wishes to appeal the decision, the decision of the Arbitrator will stand and must be complied with.

15.7.3. All substantiated decisions will be published on the CGPA website, subject to redaction of any personal information or confidential or proprietary business information. The CGPA will ensure that such decisions are published on its website within thirty (30) business days of the final resolution of any proceeding for a period of one (1) year. A summary of all decisions will also be published in the CGPA annual report.