

February 5, 2010

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

Canadian Generic Pharmaceutical Association (CGPA)

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

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1. Introduction

The Canadian Generic Pharmaceutical Association (CGPA) is the trade association representing Canada's generic pharmaceutical industry. Its membership is comprised of companies that specialize in the production of quality, affordable generic pharmaceutical products and fine chemicals, and in conducting the clinical trials required for government approval of generic medicines.

CGPA is a member of the International Generic Pharmaceutical Alliance (IGPA), an organization with which the national associations representing generic pharmaceutical manufacturers in Canada, the United States, the European Union, India and Japan are affiliated

Generic pharmaceutical products are those pharmaceutical products that have been approved by Health Canada as being equivalent to an existing brand-name pharmaceutical product.

CGPA has developed a Code of Marketing Conduct, which will govern the relationships between the suppliers of generic pharmaceutical products and their customers. This code will also enhance transparency in the generic pharmaceutical value chain, thus allowing governments to better manage their drug benefit programs. It is also designed to operate within the various legislative, regulatory and policy environments governing the sale of generic pharmaceuticals in Canada.

Any questions regarding this document or about generic pharmaceutical products in general should be directed to:

Canadian Generic Pharmaceutical Association

4120 Yonge Street, Suite 409, Toronto, ON M2P 2B8

Tel: 416-223-2333 Fax: 416-223-2425

Website: www.canadiangenerics.ca E-mail: info@canadiangenerics.ca

2. Background to this Document

The administration and enforcement of the Code of Marketing Conduct is the responsibility of the National and Quebec Industry Practices Review Boards, which has the authority to assess penalties for breaches of this code. In certain jurisdictions in Canada, provincial authorities may impose rules of marketing conduct that generic manufacturers must follow. These rules may be specified by legislation, regulation or policy. Where such rules exist they are the responsibility of the Agency charged with overseeing the drug program in the relevant jurisdiction. For example in Ontario the Agency would be the Executive Officer of the Ontario public drug program, whereas in Quebec RAMQ performs the function. (The entity performing this function is referred to as the Agency in this document).

Penalties for breaches of this code will be assessed by the National and Quebec Industry Practices Review Boards and these are separate from any action by a provincial authority. The Boards will consist of the senior sales person of each of the manufacturers whose products are available in Ontario and Quebec, whether or not they are member of CGPA, as well as the President of CGPA. From time to time the Boards can recommend to the Executive Committee of CGPA changes to the Code of Marketing Conduct that it decides are required. The final decision regarding the implementation of those changes will rest with the Executive Committee. When a potential breach of the Code of Marketing Conduct is brought to the attention of the Board, the Board will engage an independent external arbitrator to determine whether or not an actual breach has occurred. If the arbitrator finds, or if it is found on appeal, that a definitive decision cannot be made because the Code of Marketing Conduct is ambiguous or not specific enough, the Board will recommend changes to the Code to add specificity or remove ambiguity.

This document describes what CGPA believes is an appropriate Code of Marketing Conduct and is endorsed by its member companies as well as non-members that have designated CGPA their representative by proxy.

To make this Code of Marketing Conduct fully effective, it is CGPA's belief that all suppliers of generic pharmaceutical products, whether members of CGPA or not, commit to abide by the Code of Marketing Conduct before being allowed to list products on a government drug benefit plan formulary.

Until further notice, the Code of Marketing Conduct is in effect in Ontario and Quebec only.

3. Marketing Practices

3.1. General Comments

For ease of comprehension, this document differentiates between marketing to the general public and marketing to customers of the generic industry. The Code of Marketing Conduct covers both forms of marketing.

In general, marketing programs of all kinds must adhere to all applicable federal and provincial laws and regulations. No programs shall violate, or cause to be violated, the code of ethics of the College of Pharmacists of the relevant jurisdiction.

This Code of Marketing Conduct will apply to all purveyors of generic pharmaceutical products, including manufacturers¹, agents and all others who sell generic pharmaceuticals in Canada, whether or not they are members of CGPA. The word “supplier,” as used in this document, is intended to include all of the above entities.

3.2. Marketing to the General Public

3.2.1. Advertising

3.2.1.1. All advertising and informational material issued or published by suppliers of generic pharmaceutical products must be factual, unambiguous and without misrepresentation.

3.2.1.2. All marketers of generic pharmaceutical products must comply with all regulations under *The Food and Drugs Act* that relate to advertising. Therefore selling or advertising a product prior to obtaining a Notice of Compliance for that product is not allowed.

3.2.2. Public Education

All books, leaflets, documents and other material distributed by a supplier of generic pharmaceutical products for the purpose of public education shall be considered as marketing material. Information contained in such documents must be full, factual and without intent to mislead.

¹ The term “manufacturer” includes a supplier, distributor, broker or agent of a manufacturer

3.2.3. Scholarships, Bursaries and Endowments

Suppliers of generic pharmaceutical products may decide to award scholarships or bursaries, or to make endowments. Funding a Chair in Pharmacology, or making a contribution to a hospital campaign or to a faculty of pharmacy, are examples. Such actions are consistent with the Code of Marketing Conduct.

3.3. Customer Marketing

3.3.1. Preamble

In business relationships similar to the one that exists between suppliers of generic pharmaceuticals and their customers, it is normal practice to use financial incentives in the form of allowances to encourage customers to purchase from one supplier as opposed to another. However, in Canada, governments have had concerns about such allowances being paid in the health care arena. Governments are major payers for generic prescription drugs dispensed in Canada, and they believe that allowances add to the cost of generic drugs. In the past, the amount of these allowances has not been transparent to governments and this has increased their concern about the issue. Some provincial governments have passed legislation, regulation or policy to govern payments and allowances made by generic suppliers to pharmacists.

3.3.2. Allowances

3.3.2.1. Any allowances paid, directly or indirectly, to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents, must be fully in accordance with any pertinent legislation.

3.3.2.2. Allowances paid to customers by suppliers of generic pharmaceuticals are to be used by the customer in a manner consistent with any governing legislation.

3.3.2.3. Allowances paid to third parties or to related parties in the supply chain, are prohibited, except as allowed in 3.3.2.7 below.

3.3.2.4. It is allowable under this Code of Marketing Conduct to offer a discount for prompt payment. Such a discount must be in accordance with relevant legislation and should not exceed normal industry practice for such an allowance.

- 3.3.2.5. Generic pharmaceutical suppliers will report to the Agency at regular intervals determined by the Agency, the value of professional allowances provided to each customer in as much detail as is required by the Agency.
- 3.3.2.6. Allowances paid in a jurisdiction, but which are intended to be used to gain competitive advantage in another jurisdiction, are prohibited.
- 3.3.2.7. Payments made to third or related parties for distribution and other logistical services shall be allowed, as long as such payments are in accordance with all relevant legislation and would be considered normal and reasonable for the services provided.

3.3.3. Samples and Free Goods

The provision of samples and free goods to customers is prohibited. Replacement of expired goods shall not be considered as free goods as long as the replacement is on a one-for-one basis and is in accordance with industry norms.

3.3.4. Gifts

- 3.3.4.1. Gifts or any items of material value provided, directly or indirectly, to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents, must be fully in accordance with any applicable legislation.
- 3.3.4.2. Where allowed, any such gifts must be modest in nature and expense.

3.3.5. Hospitality

- 3.3.5.1. Notwithstanding the following, all hospitality must be in full accordance with any legislation in effect in the relevant province.
- 3.3.5.2. Meals or other forms of entertainment provided to customers, employees of customers or to other health-care professionals must be modest in nature and expense and shall not exceed \$500² per pharmacy customer per year. All entertainment provided should meet high ethical standards in keeping with the professional image of the generic pharmaceutical industry and of the general healthcare industry. The frequency of such entertainment with any given customer should also be reasonable.

² Under current regulations in both Ontario and Quebec, no such advantage may be provided to pharmacists.

3.3.5.3. The combined value of gifts (3.3.4.) and hospitality (3.3.5.) shall not exceed \$500³ per pharmacy customer per year.

3.3.6. Continuing Education

3.3.6.1 Travel and accommodation expenses may not be paid for customers, employees of customers or other health care professionals except where such travel is related to relevant and generally recognized accredited conventions or seminars held in Canada. To qualify, such seminars and conventions must devote the majority of the time to continuing education and other topics pertinent to patient well-being and care. Each such seminar or convention is considered as one occasion and is thus limited to the spending guidelines (excluding travel and accommodation) outlined in sections 3.3.4. and 3.3.5. Under no circumstances may spousal or companion travel expenses be paid for by generic suppliers.

3.3.7. Consultants/Advisory Boards

3.3.7.1. Suppliers of generic pharmaceutical products may wish to use health-care practitioners as consultants to advise them on aspects of their business. They may also decide to create an advisory board composed of health-care professionals to assist them in the running of their businesses.

3.3.7.2. In order to explicitly ensure that there is no conflict between the duties of such consultants or advisory boards to the company, and the other professional obligations of such consultants or advisory boards, a written contract shall exist between the company and the consultant or advisory board. This contract will specify the nature of the interaction between the company and the consultant or advisory board.

3.3.7.3. Travel expenses for attendance at advisory board meetings may be paid to advisory board members. Payment of reimbursement shall only be for travel within Canada. No travel expenses will be reimbursed for spousal or companion travel.

³ Under current regulations in both Ontario and Quebec, no such advantage may be provided to pharmacists.

3.3.8. Advertising and Sponsorships

- 3.3.8.1. The purchase of advertising or sponsorships authorized by the relevant legislation, regulation or policy at an event involving the participation of pharmacists or pharmacy customers must not exceed their legitimate commercial value.

3.3.9. Suppliers' Representatives

- 3.3.9.1. Suppliers' representatives shall behave in a professional and courteous manner when contacting health-care professionals, including pharmacists, physicians and nurses.
- 3.3.9.2. Any information provided by suppliers' representatives, whether printed or verbal, must be full, factual and without misrepresentation.
- 3.3.9.3. Sales of generic pharmaceutical products must be in accordance with federal and provincial laws and regulations.
- 3.3.9.4. Representatives will be appropriately trained to carry out their duties and will be familiar with the Code of Marketing Conduct and relevant legislation governing the sale of generic pharmaceutical products. Each representative must take and pass the standard industry-approved program once this Code of Marketing Conduct has been adopted and/or upon hiring and will agree in writing to adhere to the Code. Thereafter each representative must take and pass the program annually.
- 3.3.9.5. Companies will be held responsible for the behaviour of their representatives. It is also expected that companies will take the necessary legal steps to ensure that representatives act in a manner consistent with the Code of Marketing Conduct.

4. Audit and Verification

- 4.1. Each supplier of generic pharmaceutical products shall maintain adequate records of the nature and amount of all of its spending by customer.
- 4.2. Each supplier of generic pharmaceutical products will report all payments or commitments made to, or for the benefit of, customers and the value of all allowances provided to customers, at regular intervals as determined by the Agency. Additionally, designated officers of the reporting company will certify the accuracy of the reports as required by law or regulation.
- 4.3. Each supplier of generic pharmaceutical products will, to the best of its ability, assist the Agency or its representatives in conducting an audit. Suppliers of generic pharmaceutical products will make such records available to the Agency or its appointed representatives as required, so that the Agency can verify adherence to the Code of Marketing Conduct. The Agency will also have the right, on a confidential basis, to interview employees of suppliers of generic pharmaceutical products.
- 4.4. Where a complaint has been assigned to an arbitrator by the National or Quebec Industry Practices Review Board the suppliers of generic pharmaceuticals will assist the arbitrator in his deliberations by making relevant information available to the arbitrator, as requested. Failure by the company against which the complaint is being made to comply with this clause will result in a determination of contravention of the Code of Marketing Conduct by the arbitrator.

5. Complaint Procedure

5.1. Allegation

- 5.1.1. A supplier of generic pharmaceuticals can expose a breach of the Code in writing to one of the industry practices review boards upon payment of an amount of \$1,000. An individual or legal entity other than a supplier of generic pharmaceuticals can also expose a breach of the Code, at no charge.
- 5.1.2. The allegation must be made in writing and signed by the informant or his or her duly authorized representative (hereafter known as the “informant”).
- 5.1.3. The allegation must include the following elements:
- i) the identity of the company in alleged breach of the Code
 - ii) the nature of the alleged breach
 - iii) the date and place where the alleged breach was reportedly committed
- 5.1.4. The allegation must be tabled within six (6) months of the alleged breach.
- 5.1.5. The identity of the informant shall remain confidential and shall at no time be communicated to representatives of the companies represented on the relevant industry practices review board.

5.2. Investigation

- 5.2.1. In compliance with section 5.1. of the Code, the relevant industry practices review board shall appoint an investigator within ten (10) days of receipt of the allegation.
- 5.2.2. Within the framework of the investigation, the investigator may:
- i) summarily reject allegations received if he/she deems that elements raised do not, on the surface, make it possible to determine whether or not the Code has been breached
 - ii) question the informant or the company accused of the breach on all facts or proof relating to the alleged breach
 - iii) question, upon authorization of the informant or the company accused of the breach, the pharmacist(s) or organization(s) related to the accused breach
 - iv) require the transmission of all documents or elements of proof deemed necessary within the framework of the investigation

- 5.2.3. The company accused of the breach is required to collaborate with the investigator subject to sanctions.
- 5.2.4. The investigative process shall be conducted under the supervision of the relevant industry practices review board, to which the investigator is required to issue a report on the steps followed.
- 5.2.5. The investigation shall end no later than thirty (30) days following the appointment of the investigator.

5.3. Complaint

- 5.3.1. Within ten (10) days of the end of the investigation, if the investigator considers that the elements gathered are sufficient to establish that the Code has been breached, a complaint shall be filed with the relevant industry practices review board. Otherwise, a rejection notice shall be issued.
- 5.3.2. The complaint or rejection notice must be in writing.
- 5.3.3. The complaint filed must include the following elements:
 - i) the identity of the company alleged to have breached the Code
 - ii) the nature of the alleged breach
 - iii) the date and place of the alleged breach
 - iv) the disclosure of all facts provided in support of the accusation of the alleged breach
- 5.3.4. The rejection notice must include the reasons for the allegation's rejection.
- 5.3.5. The complaint or notice of rejection shall be communicated, upon receipt, to the informant and company alleged to have breached the Code by the relevant industry practices review board.

5.4. Hearing

- 5.4.1. Upon receipt of a complaint, the relevant industry practices review board shall appoint an independent, outside arbitrator to rule on its validity
- 5.4.2. Within five (5) days of the complaint's receipt, a notice showing the place, date and time of the hearing shall be sent by the arbitrator to the relevant industry practices review board as well as the investigator and company that allegedly breached the Code.
- 5.4.3. the hearing shall start within thirty (30) days of receipt of the complaint.

5.4.4. Within five (5) days preceding the hearing, the investigator and the company alleged to have breached the Code shall make full disclosure of proof, including:

- i) the list of witnesses and the contents of their testimony
- ii) transmission of material or written facts

5.4.5. The arbitrator shall ensure the presence of an official stenographer at the hearing, in order to provide a transcription of the proceedings.

5.4.6. The hearing shall be held behind closed doors and participants shall ensure the confidentiality of elements revealed within the framework of the hearing.

5.5. Decision

5.5.1. The arbitrator shall render a motivated decision within fifteen (15) days following the end of the hearing.

5.5.2. The decision shall be communicated to the relevant industry practices review board, the informant, the investigator and the company alleged of breaching the Code.

5.5.3. The contents of the decision rendered shall remain confidential.

5.6. Costs

5.6.1. When a complaint is deemed to be unfounded, the informant shall assume arbitration costs, except in cases where the informant is an individual or legal entity other than a supplier of generic pharmaceuticals.

5.6.2. When a complaint is found to be valid, the company alleged to have committed the breach shall assume arbitration costs.

6. Penalties

- 6.1. A company found to be in breach of its collaborative obligation, as stipulated in paragraph 5.2.3. of the Code, shall be subject to a fine of \$5,000.
- 6.2. For activities which are found to be in breach of the Code of Marketing Conduct the following penalties will apply for violations in any twelve-month period in addition to any penalties which may have been assessed under clause 5.1. above:
- 1st offence: A fine of \$15,000
- 2nd offence: A fine of \$40,000
- 3rd and subsequent offences: A fine of \$100,000
- 6.3. All breaches of the Code of Marketing Conduct will be posted on a special section of the CGPA website. This posting will name the company, the nature of the infraction and the amount of the fine and will remain on the website and be publicly accessible for a period of one year from the date of the infraction.

7. Appeals

- 7.1. Any supplier of generic pharmaceutical products found by the Agency to be in violation of the governing legislation, may appeal the decision of the Agency as specified in the relevant legislation.
- 7.2. A supplier of generic products which is found to be in violation of the Code of Marketing Conduct may appeal the decision of the National or Quebec Industry Practices Review Board. The parties to the appeal process will be as follows:
 - A representative of the party found to have been in breach of the Code
 - Three independent arbitrators appointed by the National or Quebec Industry Practices Review Board

The appeal decision will be made by the independent arbitrators and will be final and binding on both parties.