Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

Code of Conduct for Biosimilar Products in Canada

Effective October 1, 2025

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Date Adopted:	**July 1, 2025**
Effective:	**October 1, 2025**

CODE OF CONDUCT FOR BIOSIMILAR PRODUCTS IN CANADA

1. INTRODUCTION

Biosimilar Canada

The members of Biosimilars Canada 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 Biosimilar Products.

Biosimilars Canada is a division of the Canadian Generic Pharmaceutical Association ("CGPA"). Biosimilars Canada is a trade association representing Canada's Manufacturers and distributors of Biosimilar Products and suppliers of other goods and services to the biosimilar industry.

Capitalized terms have the meanings ascribed thereto in section 2 herein or as otherwise defined in this Code.

Code of Conduct

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

The purpose of this Code is to:

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

- Ensure that Manufacturers operate in a responsible, ethical and professional manner through a self-regulated approach;

- Identify the unique objectives of the biosimilar industry in its relationship 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 Biosimilar Products.

Although the industry has a legitimate right to encourage the use of Biosimilar 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 Biosimilar Products.

Scope

This Code applies to all activities of Biosimilars Canada members, their Representatives, and other third parties acting on Manufacturers' behalf, as those activities pertain to Biosimilar Products. This Code does not apply to activities relating to raw materials, non-prescription products, natural health products, medical devices and/or generic medicines.

Biosimilars Canada members must submit an Annual Attestation (in the form provided by Biosimilars Canada) signed by its most senior officer (or designate) certifying that such member is compliant with the minimum standards set out in this Code. The executed Annual Attestation must be sent to Biosimilars Canada by email at info@biosimilarscanada.ca each calendar year by January 31.

Although this Code has no authority over non-members of Biosimilars Canada, all biosimilar Manufacturers are encouraged to adhere to the principles outlined in this Code on a voluntary basis. In certain provinces, adherence to a code of conduct may be mandatory in order for a Manufacturer to get its products listed on the public drug insurance program formulary.

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

Enforcement

Complaints under this Code are considered by an arbitrator appointed by the President of Biosimilars Canada 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 17.7.3.

Contact and Allegation of Breach

Any allegation of breach of this Code by a Manufacturer, or any questions regarding this Code or about Biosimilar Products in general should be directed to:

Biosimilars Canada
4100 Yonge Street, Suite 501, Toronto, ON, M2P 2B5
Tel: 416-223-2333 Fax: 416-223-2425
Website: www.biosimilarscanada.ca
Email: info@biosimilarscanada.ca

2. DEFINITIONS

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

"**Biosimilar Product(s)**" means a biologic drug that is highly similar to a biologic drug that has already been authorized for sale by Health Canada.

"**Educational Activity**" means an accredited or an unaccredited program or activity where medical/scientific information is presented to Healthcare Professionals by their peers. An Educational Activity must be non-promotional.

"**Manufacturer(s)**" means the members of Biosimilars Canada, and all other manufacturers, suppliers or distributors of Biosimilar 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 Biosimilar Product(s), 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 as well as Healthcare Professionals or Government.

"**General Public**" means all the people who are not members of a particular medical, pharmaceutical or scientific organization or who do not have any special type of medical or scientific knowledge, which excludes persons who have been prescribed a health product by a Healthcare Professional.

"**Government**" means any federal, provincial or territorial 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 healthcare 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)**" means any person to whom a medicine has been prescribed and for which a Biosimilar Product has been/is to be dispensed.

"**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 activities of Manufacturers relating to Biosimilar 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, 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 Biosimilar Products for all Canadians;
2. Encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate use of Biosimilar 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 Biosimilar Products that is both readily accessible and transparent;
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;
5. Manufacturers should not engage in any conduct, including when discharging any obligations under this Code, that could reasonably be expected to, or in fact does, bring the biosimilar industry into disrepute, reduce public confidence in the industry, interfere with a Healthcare Professional's independence or constitute an inducement to influence the present or future professional practice of any person or organization; and
6. Contemporaneous written records of any financial or other assistance, including the provision of any items of material value, that is provided pursuant to this Code must be maintained with sufficient detail to demonstrate compliance with this Code.

Manufacturers must at all times comply with all applicable laws and regulations. To the extent that any such laws or regulations conflict with any provision of this Code, the applicable law and/or regulation governs.

4. ADVERTISING AND INFORMATIONAL MATERIAL

4.1. All advertising and informational material disseminated by a Manufacturer, 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. Biosimilar Products 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 Drugs Act*, and all other applicable laws and regulations.

5. SCHOLARSHIPS AND BURSARIES

5.1. Manufacturers may offer financial assistance for scholarships or other educational funds to, and for the benefit of, students and Healthcare Professionals in training, 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.

6. ALLOWANCES AND REBATES

6.1. Any allowances or rebates granted, directly or indirectly, by a Manufacturer 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 as a reduction on the purchase price of Biosimilar Products. If a good or service is provided, 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.

7. SAMPLES AND FREE BIOSIMILAR PRODUCTS

7.1. The provision of samples to an authorized Healthcare Professional 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.

7.2. Replacement of expired Biosimilar 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 Biosimilar Product and is in accordance with industry norms.

7.3. Biosimilar Products may be provided at no cost for humanitarian/compassionate use, unless prohibited by applicable laws and regulations.

8. SERVICE-ORIENTED ITEMS & GIFTS

8.1. Manufacturers may occasionally provide an item of material value (being worth $75.00 or more) to a Healthcare Professional so long as it serves an educational function and purpose.

8.2. Manufacturers may occasionally provide gifts to Healthcare Professionals provided the gift is less than $75.00.

9. MEALS

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

9.2. Modest and occasional meals 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.

9.3. The selection of venues for such interactions organized by a Manufacturer must be appropriate and conducive for the business meeting or events.

10. ENTERTAINMENT AND RECREATION

10.1. Manufacturers shall not organize or provide recreational activities/events or similar entertainment.

11. EDUCATIONAL ACTIVITIES

11.1. Manufacturers may sponsor an Educational Activity, provided that Manufacturers adhere to the standards issued by Health Canada and by applicable provincial and national professional bodies in so doing.

11.2. The reasonable travel, accommodation, and out-of-pocket expenses incurred by Healthcare Professionals for attending, speaking, and/or moderating an Educational Activity may be reimbursed by Manufacturers, though no payment or reimbursement may be made in respect of anyone travelling with the Healthcare Professional. Subject to the terms of this section, Manufacturers must not provide any further remuneration or compensation of any kind to a Healthcare Professional to attend an Educational Activity.

11.3. Manufacturers may retain the services of a Healthcare Professional as a speaker or as a moderator for an Educational Activity. The choice of the Healthcare Professional should be made based on that Healthcare Professional's general expertise, reputation, communication skills, knowledge and experience regarding a therapeutic product or area. A Healthcare Professional who acts as a speaker or a moderator may be paid fair market

compensation by a Manufacturer once those services have been rendered. A written contract must be in place in advance between the Manufacturer and the Healthcare Professional specifying (at a minimum) the nature of the services to be rendered, any reimbursement to be provided, and any other compensation or benefit to be provided to the Healthcare Professional.

11.4. The venue of any Educational Activity should be reasonably appropriate in all respects, including by not being extravagant or lavish, in keeping with the purpose and circumstances of the activity.

11.5. To the extent that any Manufacturer provides any support (financial or in-kind) in respect of an Educational Activity, an appropriate acknowledgement of sponsorship should appear on program related materials.

12. CONSULTANTS/ADVISORY BOARDS

12.1. 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.

12.2. 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.

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

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

12.5. 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.

12.6. 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.

13. ADVERTISING OR BRAND PROMOTION PROGRAMS

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

13.2. 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.

14. SPONSORSHIP OF THIRD-PARTY EVENTS

14.1. Manufacturers may sponsor an activity with scientific, educational, external policy shaping, advice seeking or other commercial or professional purposes, 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 commercially reasonable practices, including in terms of the quantum of the sponsorship, and if quantifiable, the fair market value.

14.2. Nothing contained herein shall prevent a Manufacturer from supporting, including through sponsorships, any charitable or non for profit organizations for the purposes of participating in fundraising activities for any such organization.

15. PATIENT SUPPORT PROGRAMS

15.1. Patient support programs (“PSPs”) offered by Manufacturers must be designed and implemented to benefit Patients, facilitate access to relevant treatments, and/or enhance Patients’ understanding of the applicable medical condition(s) and treatment(s).

15.2. Manufacturers should not retain the services of a prescribing Healthcare Professional in connection with that Healthcare Professional’s own Patient(s) and the offered/provided PSP.

16. TRAINING OF REPRESENTATIVES

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

16.2. Manufacturers should ensure that all Representatives who are acting on their behalf, and who have interactions with Healthcare Professionals and/or

Customers receive periodic training on this Code, and about all applicable laws and regulations.

16.3. 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.

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

17. ENFORCEMENT

17.1. Enforcement

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

17.1.2. 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.

17.2. Allegation of breach

17.2.1. 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.

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

17.2.3. 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.

17.2.4. 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.

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

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

17.3. **Investigation**

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

17.3.2. 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.

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

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

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

17.3.6. 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.

17.4. **Complaint**

17.4.1. 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 Biosimilars Canada (the "Complaint"). Otherwise, a rejection notice shall be issued.

17.4.2. The Complaint or rejection notice must be in writing.

17.4.3. The 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.

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

17.4.5. The Complaint or notice of rejection shall be communicated, upon receipt, to the Complainant and Respondent by Biosimilars Canada.

17.4.6. All information pertaining to the Allegation and to the 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.

17.5. **Hearing**

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

17.5.2. 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 Biosimilars Canada may adopt written rules of procedure to be followed by the Arbitrator in the course of reviewing any Complaint.

17.6. **Decision**

17.6.1. 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 Board of Biosimilars Canada.

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

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

17.6.4. When a 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.

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

17.7. **Sanctions**

17.7.1. 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 Biosimilars Canada 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 Biosimilar 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 Biosimilar 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 Biosimilar 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 Biosimilars Canada Board to terminate the membership of the Respondent from Biosimilars Canada.

17.7.2. 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.

17.7.3. All substantiated decisions will be published on the Biosimilars Canada website, subject to redaction of any personal information or confidential or proprietary business information. Biosimilars Canada 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.