



**Canada's Drug Agency**  
**L'Agence des médicaments du Canada**  
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

# **Supplemental Conflict of Interest Guidance Document**

Effective/Revised Date: October 1, 2022

Review Period: Every 3 years

Version: 1.0



### Introduction

1. Please be advised that this guidance document is not a substitute for the [Conflict of interest policy](#) (the “policy”) and both documents must be read together.
2. The purpose of this guidance document is to outline the conflict of interest process and provide examples to help Canada’s Drug Agency (CDA-AMC) constituents understand and apply the policy to their individual circumstances.
3. In the event of any inconsistency between this guidance document and the policy, the policy shall prevail to the extent of the inconsistency.

### Guiding Principles

3. Conflict of interest declarations are the foundation for trustworthy advice and products.
4. Having a conflict of interest is not unethical, nor does it preclude involvement or mean that input will automatically be discounted.
5. Identifying conflicts of interest ensures that the effects of interests are known, so any potential biases can be understood. This allows appropriate management measures to be implemented to mitigate the conflict and protect the objectivity of the work or decision-making process.
6. Being transparent about the interests of those who are engaged and involved in CDA-AMC’s work and governance allows stakeholders to form their own judgment about the information with the full disclosure of the facts.
7. To protect individual privacy, CDA-AMC will apply the principle of least privilege to the handling of declarations. Please refer to the applicable constituent supplement (as detailed in section 21) for additional information. Access to declarations will be limited to the designated CDA-AMC staff or assigned board, committee, or panel members, and only as needed to perform their assigned responsibilities (e.g., review, approve).



### Declaration Requirements

8. All individuals engaged and involved with CDA-AMC's work and/or governance are responsible for reading and understanding their obligations under the policy.
9. Before an individual engages with or participates in any CDA-AMC-related role or activity, the individual must disclose any conflicts of interest as defined in the policy (refer to sections 7 and 8).
10. All interests must be declared if, in the view of a reasonable person, they are relevant or could be perceived to be relevant to the CDA-AMC mandate, activity in question, or anticipated future activity, as may be applicable. This includes interests or activities that have occurred during the past 2 fiscal years, and any potential or pending future commitments, which could affect or appear to affect an individual's objectivity or fairness.
11. It is recognized that there could be a situation where a CDA-AMC constituent has a conflict of interest that arises from their personal health circumstances, or the personal health circumstances of a close family member or friend. To limit intrusion into the personal health circumstances of CDA-AMC constituents:
  - a) only conflicts of interest that meet the threshold of being sufficient (real or perceived) to bias or influence the objective exercise of the constituent's CDA-AMC-related duties, responsibilities, or decision-making should be declared
  - b) when declaring a conflict arising from personal health circumstances, CDA-AMC constituents should simply identify that they have a "relevant interest" to a specified topic (or project). Personal health information, such as diagnoses, medical conditions, and medications, should not be included in the declaration
  - c) if further information is required for CDA-AMC to assess and manage a declared conflict of interest, the individual may be contacted to discuss the nature of the conflict. CDA-AMC constituents are under no obligation to disclose any personal health information. As part of this discussion, CDA-AMC constituents may choose to disclose personal health information to CDA-AMC on a confidential basis to assist with the management of the declared conflict. Any confidential personal health information that a



## Supplemental Conflict of Interest Guidance Document

CDA-AMC constituent chooses to disclose will be used only for the limited purpose of determining how to appropriately manage a conflict of interest.

12. CDA-AMC constituents are required to disclose any past, potential, and/or pending future activities related to the CDA-AMC Scientific Advice Program or any similar international programs.
  - a) This disclosure is required for any work that CDA-AMC may perform related to drugs that have received advice from these programs.
  - b) CDA-AMC considers it to be a conflict of interest for an individual who has participated in developing scientific advice for a given drug to later participate in a review for the same drug when it is submitted to CDA-AMC through the CDA-AMC Reimbursement Review Program.

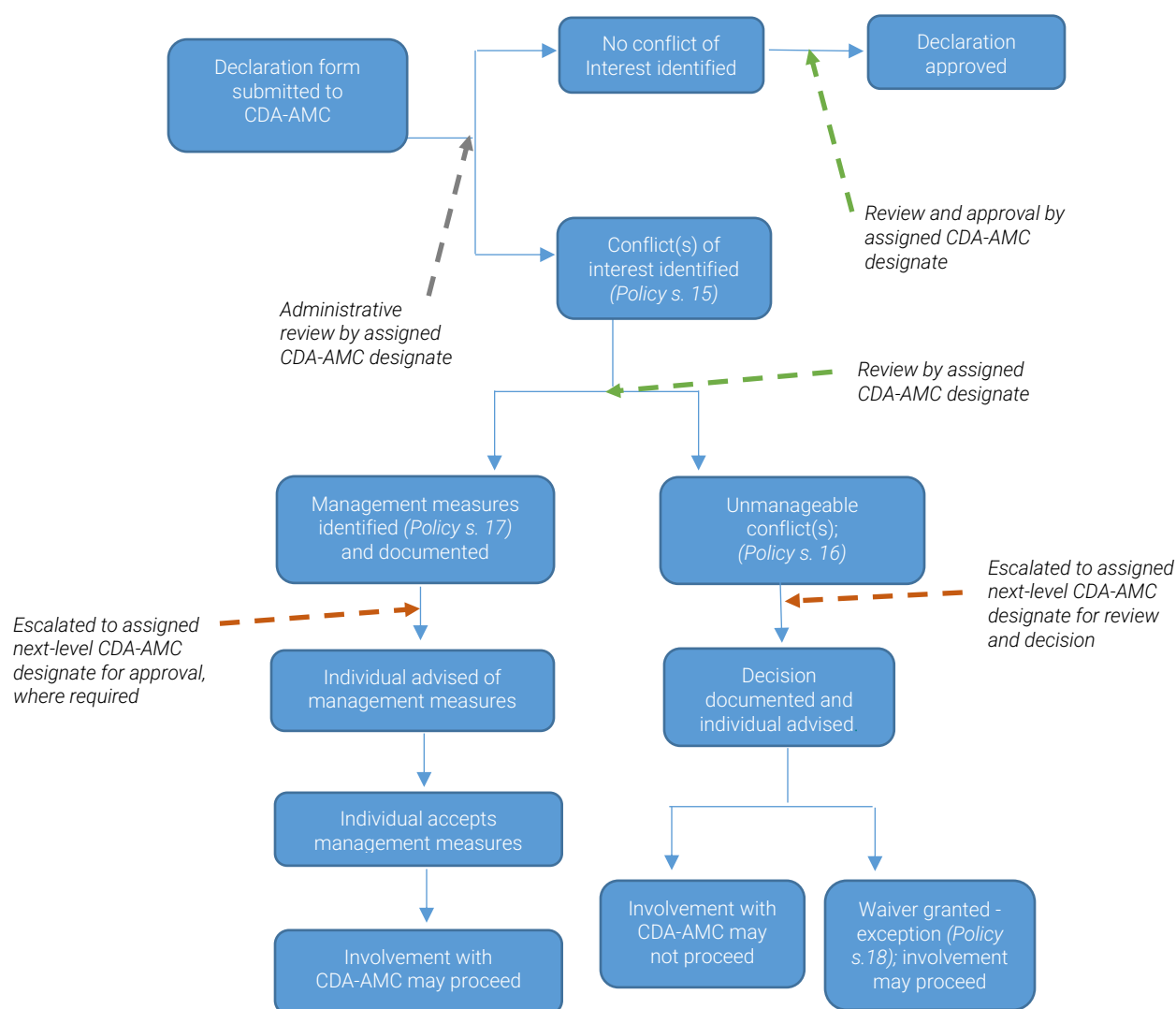
## Reviewing, Assessing, and Managing Conflicts

13. The range of interests, interactions, and experiences of individuals, and the breadth and reach of CDA-AMC's work, make it likely that conflicts of interest will arise. CDA-AMC will work with the individual or party to resolve or manage conflicts in a manner that protects the integrity of CDA-AMC's work and decision-making, while creating space for a range of perspectives and expertise.
14. Where a conflict of interest is identified, CDA-AMC will assess all the relevant factors on a case-by-case basis. Resolution or management measures required will be dependent on both the nature of the conflict and structure of the activity. Please refer to sections 15 to 18 of the policy for additional information.
15. CDA-AMC has the authority to:
  - a) determine if the circumstances or interests of a CDA-AMC constituent (i.e., a group listed in section 1 of the policy) amount to a conflict of interest with respect to work being undertaken by CDA-AMC
  - b) remove a CDA-AMC constituent from a project or work when it is deemed that the conflict of interest(s) could impede their objectivity (real or perceived).
16. There may be situations when interests will not be identified, declared, or managed appropriately and effectively. This may happen innocently, accidentally, or because of deliberate actions. In view of the shared goal of preserving the integrity of CDA-AMC's work, anyone who is aware of a contravention with the

policy, or who is concerned that there has been, or may be, an issue of non-compliance, should follow these steps:

- Speak directly to the individual or party who is believed to have the conflict, where possible.
- If the issue is not resolved, the concern should be directed to the CDA-AMC President and CEO via email at [suzanne.mcgurn@cda-amc.ca](mailto:suzanne.mcgurn@cda-amc.ca).
- The President and CEO will examine each reported instance of potential contravention according to its specific facts and merits and will determine and implement the appropriate remedy or management measures, as may be applicable.

### 17. Illustration of the process for conflict of interest declarations:



Note: "Conflict of interest" includes real, potential, and perceived conflicts.



## Supplemental Conflict of Interest Guidance Document

### Publication of Declarations

18. Conflict of interest declarations may be made publicly available, as identified in sections 19 and 20 of the policy.
19. Published conflict of interest declaration statements for individuals will reflect the nature of relevant interests but will not include the amount (or range) of financial interest.
20. In cases of groups or organizations submitting a collective declaration (e.g., clinician groups, patient groups) where individual financial interest is not identifiable, the range of financial interest will be publicly disclosed.

### CDA-AMC Constituent Supplements

21. Please refer to the following supplements for additional requirements and process details specific to CDA-AMC constituent types:
  - [Supplement A – Board of Directors](#)
  - [Supplement B – Employment Candidates and Employees](#)
  - [Supplement C – Members of Advisory or Expert Committees or Panels](#)
  - [Supplement D – Participants](#)
  - [Supplement E – Contributors](#)
  - [Supplement F – Contractors](#)
  - [Supplement G – Guest Speakers](#)

### Examples of Conflicts of Interest

When preparing your declaration, please review the scope of conflict of interest defined in the policy (refer to sections 7 and 8).

A conflict of interest is any situation in which an individual has or is perceived to have a personal, non-personal, or other relevant interest sufficient to bias, influence, or appear to influence the objective exercise of that individual's CDA-AMC-related duties, responsibilities, or decision-making.

The following sections provide examples of personal interests, non-personal interests, and other relevant interests; the list of examples is non-exhaustive and is intended for illustrative purposes only.

If you are uncertain as to whether an activity or situation could represent a conflict, please get in touch with a designated CDA-AMC staff member for advice and guidance.



### Personal Interests

**Personal interests** are benefits to you, in any form (financial and non-financial), by a party or entity whose business may be directly affected by CDA-AMC advice or other decisions taken by CDA-AMC. This benefit is interpreted broadly and means anything relating to your interests (regardless of value), now or in the future. Examples may include:

- Employment: past or current employment with any drug or medical device manufacturer, including parent corporations, subsidiaries, affiliates, and consulting companies providing services to these firms.
- Expenses/Hospitality: expenses or hospitality provided by a party should be declared. Expenses or hospitality beyond that reasonably required for accommodation, meals, and travel to attend meetings and conferences might reasonably be perceived as affecting an individual's impartiality.
- Fee-paid work: any work commissioned by a party or entity for which you are paid in cash or in kind.
- Funding or honoraria: funding received for speaking engagements, giving educational lectures, organizing conferences, writing articles or editorials, research grants or unrestricted grants, personal education, academic appointments (including endowed chairs), and so on.
- Gifts: gifts of material value (i.e., beyond the cost of a normal lunch or dinner), offered or tendered by virtue of your involvement with CDA-AMC.
- Intellectual property rights: patents, copyrights, and royalties from these rights.
- Investments: funds held in a portfolio in which you and/or your immediate family have the ability to instruct the fund manager as to the composition of the fund.
- Shareholdings: any shareholding or other beneficial interest in a party where you have influence on financial management.
- Loyalties: any loyalty arising from a personal connection or duty to another person or organization (e.g., past employer, former student, family member, close colleague).
- Reputational interest: any situation where your objectivity could be influenced because there is a benefit or a cost to your reputation, depending on the outcome of the matter under consideration by CDA-AMC.

### Non-Personal Interests

**Non-personal interests** are where there is, or could be perceived to be, an opportunity for others closely associated with you — such as a family member, business associate,



## Supplemental Conflict of Interest Guidance Document

friend, or department — to benefit as a result of your role at CDA-AMC. This could be financial or non-financial. Examples may include:

- commissioning of research or other work or advice from staff who work in a unit for which you are responsible
- grants from a party for the running of a unit or department you work in, or for which you are responsible
- grants or fellowships to sponsor a post or staff member in a department or unit for which you are responsible
- holding office or a position of authority in a professional organization (e.g., clinical society/college, university, charity, or advocacy group)
- participation on a voluntary committee external to CDA-AMC in relation to a specific product
- involvement in an ongoing or scheduled trial or research project for a product under review or a competing product (e.g., participation as an investigator in clinical trials of relevance to the project or competing product)
- a family member or friend having had a major development responsibility for a product under review
- having authored or co-authored a document submitted as an evidence publication to the relevant CDA-AMC advisory committee or panel
- giving advice to, or having a close association or professional relationship with a party
- employment of a spouse or child.

### Other Relevant Interests

**Other relevant interests** are other kinds of interests with a party or entity that are relevant, depending on the circumstances and matters under consideration, which could bias, influence, or appear to influence the objective exercise of your CDA-AMC-related duties, responsibilities, or decision-making. Examples may include:

- involvement in lobbying activities (product or process related to CDA-AMC)
- having published a strong, clear opinion (either favourable or unfavourable) about a particular company, product, or class of products under consideration by CDA-AMC, or about a competitor's product or class of product
- having a strongly held belief related to a topic area that would make it difficult to perform your CDA-AMC-related work in an unbiased manner
- having been treated (or a family member or someone close to you having been treated) with a product under discussion





## Supplemental Conflict of Interest Guidance Document

- having done research work (or your department having done research work) relating to a particular product, or class of products, where the research has reached a certain conclusion (e.g., in relation to the safety of the product or its efficacy)
- having interests in a company manufacturing the delivery system for a particular medicinal product that is the subject of a CDA-AMC review
- being involved in the promotion of a product that is of relevance to, or under consideration by, CDA-AMC
- participating in, or having a connection with, a voluntary organization, patient group, or other special interest group that would have an interest in the outcome of CDA-AMC's work, or is of relevance to your CDA-AMC-related duties
- being a party to a claim, application, or proceeding for or against CDA-AMC.

### Revision History Table

Item	Description	Date
1	Document introduced	October 2022
2	Template updated	September 2024