



National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

Conflict of Interest Guidelines and Confidentiality Obligations for Members of the National Drug Scheduling Advisory Committee (NDSAC)

Conflict of Interest Declaration Members of NDSAC

I have read and understand the attached NDSAC Conflict of Interest and Confidentiality Obligation Guidelines and acknowledge that I am required to comply with them. I further acknowledge my responsibility to disclose to NAPRA all actual or perceived conflicts of interest which may exist while acting as a member of NDSAC on an ongoing basis during my relationship with NDSAC.

I declare that:

- I do not have a conflict of interest.
- I have a conflict of interest or a perceived conflict of interest.

Attached is a comprehensive written submission of the complete nature of this actual or perceived conflict of interest. I am aware that this form and the information attached to it may be submitted to NAPRA. I authorize its submission and use by NAPRA in such manner as NAPRA may in its discretion decide,

PLEASE PRINT:

Date:	Signature - NDSAC Member:
Date Received:	Signature - Chair - NDSAC:



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Conflict of Interest Guidelines and Confidentiality Obligations for Members of The National Drug Scheduling Advisory Committee (the "NDSAC Guidelines")

Overview

The following guidelines are intended to govern the disclosure and avoidance of conflicts of interest for all Committee Members and to clarify their obligations to ensure that certain information of which they become aware of remains confidential. The guidelines set out below are intended to supplement the requirements of the common law and any governing legislation including, without limitation, The Canada Corporations Act.

Article 1 - Declaration of Interests

1.1 Every Committee Member shall declare to NAPRA in writing the nature and extent of any relationship, arrangement, contract or agreement which creates a duty to or interest in any other person which may result in a conflict of interest, real or perceived. The declaration to be made by the Committee Member shall be in the form annexed as Schedule "A" to these guidelines (the "Declaration").

1.2 Every Committee Member shall file, not less than annually, an updated Declaration. If at any time during the year following the filing of his or her Declaration there occurs any material change in the information contained in the Declaration given by the Committee Member, either by way of addition or deletion, that Committee Member shall forthwith file a supplementary Declaration describing such change.

Article 2 - Disclosure of Conflicts and Participation

2.1 Every Committee Member has any interest in any matter or thing before the Committee in respect of which the Committee will be rendering a decision shall orally disclose the nature and extent of his or her Interest to the Chair of the Committee and provide a written Declaration if requested by the Chair,

2.2 Without restricting the generality of the immediately preceding paragraph, the Committee Members shall be deemed to be interested in a matter where he or she knows or, in the circumstances should know, that any associate of his or hers has an interest in such matter.

2.3 A Committee Member who is interested in a matter shall not participate in any discussion or decision by the Committee regarding that matter. The disclosure required by the Committee Member shall be recorded in, or annexed to, the minutes at the meeting at which such disclosure was made or the minutes of the next meeting following such disclosure.

Article 3 - Non-Compliance with Guidelines

3.1 In the event of any allegation of non-compliance with these guidelines, the Board of Directors of NAPRA (the "Board") may investigate into and determine the validity of such allegations. The Board shall take such steps and measures as the Board may, in its sole discretion, determine appropriate, including and without limitation, declaring that the Committee Member has breached these



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guidelines and is no longer qualified to serve as a Member of the Committee and that his office is thereby vacated; provided that, the Board of Directors shall first advise the Committee Member in writing of the nature and extent of such allegations and provide the Member with an opportunity to make representations regarding same.

Article 4 - Confidentiality and Non-Disclosure

4.1 In the course of performing his or her duties as a Member of the Committee, the Committee Member shall become aware of the Proprietary Information of manufacturers or others involved in the development, manufacture or distribution of drugs in Canada (the "Disclosing Person"). Except as hereinafter specified, the Committee Member agrees not to directly or indirectly use or exploit such information, to hold such proprietary information in confidence without disclosure to any third party and to protect it against unauthorized use and disclosure as would a reasonably prudent owner of such proprietary information. The Committee Member may disclose proprietary information to the extent reasonably necessary for perform his or duties as a Member of the Committee provided that any such disclosure shall be made on a "need to know" basis.

4.2 The restrictions set out in paragraph 4.1 above shall not apply to:

(i) information divulged or used by the Committee Member after receiving the Disclosing Person's express written consent thereto;

(ii) information already known to the Committee Member without restriction on full disclosure as evidenced by such Committee Members records;

(iii) information rightfully obtained by the Committee Member from a third party without restriction-

(iv) information independently developed by the Committee Member, from and after the date of any such disclosure; and

(v) information that, at the time of receipt, was in the public domain, or becomes public domain information through no breach of the confidentiality obligations by any member of the Committee, or any employee, member, director or agent of NAPRA.

Article 5 - Interpretation

5.1 For the purposes of these guidelines, the following words or phrases shall have the meanings set out below.

"**Affiliate**" shall have the meaning attributed to it by the Canada Business Corporations Act;

'**Associate**' when used to indicate a relationship with any person, means:

(i) a body corporate of which that person beneficially owns or controls, directly or indirectly, shares or securities currently convertible into share carrying more than one percent (1%) of the voting rights under all circumstances or by reason of the occurrence of an event that has occurred and is continuing, or a currently exercisable option or right to purchase such shares or such convertible securities,



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- (ii) a partner of that person acting on behalf of the partnership of which they are partners;
- (iii) a trust or estate in which that person has a substantial beneficial interest or in respect of which he serves as a trustee or in similar capacity;
- (iv) a spouse or child of that person; and
- (v) a relative of that person or of his spouse if that relative has the same residence as that person.

"Board" means the Board of Directors of NAPRA-

"Decision" means any determination, grant, or any other decision in connection with any matter relating to recommendations regarding the scheduling of drugs in Canada including, without limitation, determinations of the appropriate schedule for a drug, recommendations on the conditions and place of sale of drugs in Canada and evaluation and maintenance of the drug scheduling factors.

"Disclosing Person" shall have the meaning ascribed to in paragraph 4.1.

"Interest" includes:

- (i) a personal or business benefit or advantage;
- (ii) an increase or decrease in the value of real or personal property;
- (iii) an advantage, gain, profit, reward or perquisite of any kind, whether pecuniary or otherwise, and whether direct or indirect; or
- (iv) a duty owed as a director, officer, official, associate or employee of a Disclosing Person or any associate of a Disclosing Person.

"Participate" with respect to a decision of the Committee means to participate personally as a member of the Committee, whether through approval, disapproval, decision, recommendation, the giving of advice, voting or otherwise but does not include the discussion by an interested committee member of a decision or resolution at a meeting of the Committee where a majority of the remaining Committee Members have approved the discussion on that subject by the interested Committee Member.

"Person" means any individual, corporation, partnership, trustee or trust or unincorporated association; and pronouns have a similarly extended meaning.

"Proprietary Information" shall include information owned, possessed or controlled by the Disclosing Person which may include, but shall not be limited to;

- (i) any information, in oral, written or any other form that the Committee or NAPRA receives from the Disclosing Person and that is designated by such person as proprietary or confidential;



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(ii) any information, process or idea that is not generally known by anyone other than the Disclosing Person insofar as it relates to the business of the Disclosing Person including, but not limited to, techniques and concepts relating to the development, manufacture, distribution or sale of products or services by the Disclosing Person,

(iii) all financial information relating to the Disclosing Person;

(iv) all computer programs including algorithms, specifications, flowcharts, listings, source codes and object codes either owned by the disclosing person or which the Disclosing Person has access and wishes to keep confidential excluding a commercially available software; any secret or trade secret or know how of the Disclosing Person or any Person with which the Disclosing Person does business which is not known to persons outside the Disclosing Person, including the identity, buying habits and preferences of "customers" as well as prospective customers of the Disclosing Person.