

Guidance on Interpretation of Bylaw No. 2 and Rules of Procedure

IMPORTANT: The following is a summary of the provisions set out in [Bylaw No. 2](#) and the [Rules of Procedure](#). In the event of any inconsistency or conflict between the provisions of the Bylaw or Rules of Procedure and this information, the provisions of the Bylaw or Rules of Procedure, as applicable, shall prevail.

NAPRA will post notice of each review or reassessment and particulars of the submission on the NAPRA website with an invitation to any party who may be interested in the submission to become an [Interested Party](#) and have an opportunity to be heard. Notice can also be served by email, by fax, by mail, by courier, or in person. Individuals who have subscribed to the [National Drug Schedules \(NDS\) Updates](#) will be specifically notified.

To request Interested Party status, parties must complete the [Application for Interested Party Status](#) form and send to the [NDSAC Secretariat](#) no later than 45 days prior to the NDSAC meeting. Once NDSAC has ruled on who will be granted standing as an Interested Party, a list of such parties, with contact information, shall be prepared and forwarded to all interested parties with a direction that any information or materials which they wish to file must also be sent to each of the interested parties named on the list.

An Interested Party can request information, or a copy of any document related to a review, or reassessment of the applicant or another Interested Party. If the information is not provided as requested within 10 days, the information will be refused as evidence in the review or reassessment hearing unless NDSAC agrees with the reason(s) for not complying with the request.

These “interrogatories” and responses to these interrogatories must follow a prescribed format (see [Rules of Procedure](#)). Copies of the request and the response must be filed with the [NDSAC Secretariat](#) and must be received within time limits directed by NDSAC.

There are three possible negative responses to an interrogatory:

1. The information requested is felt to be non-relevant;
2. The information requested is not available, in which case alternative information must be provided; or
3. The information requested is felt to be confidential.

Reasons for not providing the information requested must be stated in each instance. The validity of these reasons will be assessed by NDSAC. Depending on the results of its assessment, the NDSAC can demand that the information be provided, or that alternate or abridged information be provided.

Any document provided to NDSAC will be on the public record unless the provider requests that it be held confidential and NDSAC agrees to its confidentiality, in which case an abridged version will be made available to the public, or at the least, a record of the claim for the document’s confidentiality.

NDSAC may need to study the actual document for which confidential status is being claimed or it may arrange for the claim for confidentiality to be dealt with by other means: i.e., by conference, before a commissioner of oaths or by the Committee during the oral portion of the review or reassessment proceeding (see [NDSAC Drug Scheduling Rules of Procedure re: Confidentiality](#)).

An Interested Party may request disclosure of a confidential document by filing a request and/or any material in support of the reasons for public disclosure with NDSAC. A response to such a request must be provided within 10 days.

The applicant and Interested Parties are entitled to present before the Committee. A delegation of up to three representatives may attend on behalf of the organization. Twenty minutes will be allotted for the presentation, with an additional 15 to 20 minutes for Committee questions and answers.

The [Canada Evidence Act](#) applies to all drug scheduling reviews. NDSAC may require any Interested Party or their solicitor to submit information considered necessary for a review. NDSAC can also request the attendance of any other person believed to have information relevant to the proceeding.

NDSAC may call for verification by affidavit of any information brought forward. Affidavits are to be filed with the Executive Director of NAPRA.

Non-compliance with any of NDSAC's requests can result in delays in proceedings or even suspension of the Interested Party's participation or dismissal of the application. NDSAC may refer issues of law to the appropriate court, during which time review proceedings could be delayed.

NDSAC's proposed recommendations (i.e., the "interim recommendations") and the reasons for these proposed recommendations will be published on the NAPRA website and subsequently forwarded to NAPRA's Board of Directors within seven (7) days of publication.

An Interested Party or the applicant may request a reassessment or a review or variation to an interim recommendation prior to it becoming a final recommendation. Such requests must be received in writing within 30 days of the recommendation being posted to the NAPRA website.

NAPRA's Board of Directors will confirm or reject the interim recommendations or direct that a reassessment be conducted within 15 days of the end of the 30-day review period.

The final recommendations (and the reasons) will then be published unless a reassessment has been deemed by NDSAC to be in the public interest.

Unless NAPRA decides to direct a new hearing, the interim recommendations will become final recommendations within 15 days of the end of the 30-day review period, subject to NAPRA's exercising its discretion to re-hear, review, vary or confirm the interim recommendations or final recommendations in accordance with [Bylaw No. 2](#) and the [Rules of Procedure](#).