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

Rules of Procedure

1. These Rules may be cited as the NDSAC Drug Scheduling Rules of Procedure.

INTERPRETATION

2. In these Rules,

"*interrogatory*" means any request in writing for information or particulars made to a party in a proceeding; and

"*proceeding*" means a proceeding relating to the scheduling of a drug.

"*Rules*" means the Rules of Procedure of the National Drug Scheduling Committee in regard to Drug Scheduling Proceedings, being the Schedule to By-law No.2 of the National Association of Pharmacy Regulatory Authorities; and

the meaning given to any term in any by-law of the National Association of Pharmacy Regulatory Authorities shall also be given to the same term when employed in these Rules.

APPLICATION OF RULES

3. These Rules apply to the portions of all proceedings conducted by NDSAC.

PART I - GENERAL

Holiday

4. Whenever a time limit or deadline calculated under these Rules falls on a Saturday, Sunday or statutory holiday, the time limit or deadline is extended to the next following working day.

Directions on Procedure

5. (1)Where it deems it appropriate in any proceeding, NDSAC may issue directions on procedure, which shall govern the conduct of the portion of the proceeding conducted by NDSAC and prevail over any provision of these Rules that is inconsistent with those directions.

(2) Any party making an application to NAPRA for a drug scheduling review may, as part of the application, apply to NDSAC for the issuing of directions on procedure relating thereto, and in the event that the applicant is not the manufacturer of the drug in respect of which the drug scheduling review is sought, shall also apply therein to NDSAC for standing as an interested party.

(3) Any party seeking to participate in a drug scheduling review, other than the manufacturer of the drug to which the drug scheduling review relates shall apply for standing as an interested party, and no such party shall participate in a drug scheduling

review without first obtaining such standing. The status of a party as an interested party in a drug scheduling review may be denied or revoked by NDSAC at any time, where NDSAC, in its discretion, concludes that the party's participation or continued participation in the drug scheduling review would constitute an abuse of power.

Service

6. (1) Subject to subsection (2), service of any notice or other document, including a document originated by NDSAC, shall be effected either by,

(a) personal service, in which case service shall be deemed to occur upon delivery;

(b) courier, in which case service shall be deemed to have been made on the day of receipt indicated on the courier receipt;

(c) by mail, in which case service shall be deemed to have been made on the tenth (10th) day following the day on which the notice or other document is deposited in a post office, postage pre-paid;

(d) by facsimile, in which case service shall be deemed to have been made when confirmation of transmission of the notice or other document is obtained by the party serving the document; or

(e) by electronic mail, in which case service shall be deemed to have been effected twenty-four hours after the transmission containing the notice or document was sent, unless the party serving the notice or document receives a message by electronic mail within that time period indicating that the transmission by which service was to be effected was not received by the intended recipient, and in such case serve shall be deemed not to have occurred.

(2) Personal service may be effected on NDSAC at its head office.

Affidavits

7. (1) Affidavits in proceedings before NDSAC shall be filed with the Secretary.

(2) Where an affidavit is made as to belief, the grounds on which the belief is based shall be set out in the affidavit.

Verification

8. (1) NDSAC may, at any time, require the whole or any part of any application, intervention, response to an interrogatory or other submission to be verified by affidavit by giving a notice to that effect to the party from whom such verification is required.

(2) If a notice given under subsection (1) is not complied with, NDSAC may set aside the application, intervention, response to an interrogatory or other submission or strike out any part thereof not verified in accordance with the notice.

Consequences of Non-Compliance and Stay of Proceeding

9. Where an interested party to a proceeding has not complied with any requirement of these Rules, any direction on procedure issued under section 5, or any order or requirement of NDSAC in a proceeding or in respect of a proceeding, NDSAC may stay the proceeding until satisfied that such requirement has been complied with or take such other steps as it considers just and reasonable, including without limitation, expunging all or such portion of the submissions of the interested party as it sees fit, suspending the participation of the interested party in the proceeding, or, if the interested party is an applicant, summarily dismissing the application.

Questions of Law

10. If it appears to NDSAC at any time that there is a question or issue of law, of jurisdiction or of practice and procedure that should be decided before a proceeding is continued, NDSAC may direct the question or issue to be referred to the appropriate court for decision and NDSAC may, pending such decision, order any part of the proceeding to be stayed.

Conference

11. NDSAC may, orally or in writing, require interested parties or their solicitors to attend a conference relating to any procedural or evidentiary matters with a view to making the proceeding as efficient and effective as possible.

Production

12. (1) Any interested party to a proceeding may, at any time before the hearing of the proceeding, give notice in writing to any other interested party in whose application, intervention, response to an interrogatory or other submission reference has been made to a document to produce that document for inspection by the party giving the notice or his solicitor and to permit him or his solicitor to make copies thereof.

    (2) Any interested party who fails to comply with a notice given pursuant to subsection (1) within 10 days from the receipt thereof shall not thereafter be at liberty to put the document referred to in the notice in evidence in the proceeding, unless NDSAC that the interested party had sufficient cause for not complying with the notice.

Interrogatories

13. (1) Where in any proceeding NDSAC permits interrogatories to be directed to an interested party, such interrogatories shall be,

    (a) addressed to the interested party;

    (b) numbered consecutively, but a series of numbers may be used for interrogatories relating to the same subject-matter;

    (c) identified with a designation in the following form:

"Name 1(Name 2)01Aug99-100"

where

(i) "Name 1" is an abbreviation for the party from whom the response is sought,

(ii) "Name 2" is an abbreviation for the party seeking the response,

(iii) the date is the date on which the interrogatory was sent, and

(iv) the final number is the number of the particular interrogatory; and

(d) served within the time limit directed by NDSAC.

(2) A copy of any interrogatories directed to a party pursuant to subsection (1) shall be filed with the Secretary.

Responses to Interrogatories

14. (1) Subject to subsection (2), where in any proceeding NDSAC permits interrogatories to be directed to a party and interrogatories have been served on the party within the time limit directed by NDSAC, the party shall,

(a) within the time limit directed by NDSAC, provide a full and adequate response to each interrogatory on a separate page or pages, headed as indicated in Form 1 attached hereto; and

(b) file a copy of the responses with the Secretary.

(2) An interested party who is unable or unwilling to provide a full and adequate response to an interrogatory shall,

(a) where the interested party contends that the interrogatory is not relevant, provide a response that sets out reasons in support of that contention;

(b) where the interested party contends that the information necessary to provide a response is not available, provide a response that sets out the reasons for the unavailability of such information and provide alternative available information that the interested party considers would be of assistance to the person directing the interrogatory, or

(c) where the party contends that the information sought is of a confidential nature, provide a response that sets out the reasons therefor in accordance with subsection 17(2) and file with the Secretary a copy of the response provided.

(3) Where NDSAC is of the opinion that the failure by an interested party to provide a full and adequate response to an interrogatory is not justified in accordance with subsection (2), it may require that the interested party provide a full and adequate response in accordance with further directions issued by NDSAC.

Confidentiality

15. (1) Where a document is filed with NDSAC by an interested party in relation to any proceeding, NAPRA shall place the document on the public record unless the party filing the document asserts a claim of confidentiality at the time of such filing.

(2) Any claim for confidentiality made in connection with a document filed with NDSAC or requested by NDSAC or any interested party shall be accompanied by the reasons therefor, and, where it is asserted that specific direct harm would be caused to the party claiming confidentiality, sufficient details shall be provided as to the nature and extent of such harm.

(3) An interested party claiming confidentiality in connection with a document shall file with NDSAC an abridged version of the document to be placed on the public record or his reasons for objecting to the filing of an abridged version thereof.

(4) A claim for confidentiality referred to in subsection (2) shall be placed on the public record and a copy thereof shall be provided on request to any interested party.

(5) Where a claim for confidentiality is made in connection with a document that has not been filed by a interested party, NDSAC may require the party to file the document and, after the document has been filed, the document shall,

(a) be reviewed by NDSAC in confidence; and

(b) be dealt with as provided in subsection (10) or (11), whichever is applicable.

(6) Any interested party wishing the public disclosure of a document in respect of which there has been a claim for confidentiality may file with NDSAC,

(a) a request for such disclosure setting out the reasons therefor, including the public interest in the disclosure of all information relevant to NDSAC's regulatory responsibilities; and

(b) any material in support of the reasons for public disclosure.

(7) A copy of a request for the public disclosure of a document shall be served on the interested party claiming confidentiality and that party may, unless NDSAC otherwise determines, file a reply with NDSAC within 10 days after the date of service of the request and shall, where a reply is filed, serve a copy thereof on the interested party requesting public disclosure.

(8) Where NDSAC of its own motion requests that a document be placed on the public record, the interested party claiming confidentiality shall have 10 days to file a reply, unless NDSAC otherwise determines.

(9) NDSAC may dispose of a claim for confidentiality on the basis of the documentation filed or may, if it considers such procedure to be just and proper,

(a) refer the matter to a conference under section 11;

(b) require depositions to be taken before a commissioner of oaths; or

(c) refer the matter to the oral hearing portion of the proceeding conducted by NDSAC.

(10) Where NDSAC is of the opinion that, based on all the material before it, no specific direct harm would be likely to result from disclosure, or where any such specific direct harm is shown but is not sufficient to outweigh the public interest in disclosing the document, NDSAC shall require the interested party to place the document on the public record.

(11) Where NDSAC is of the opinion that, based on all the material before it, the specific direct harm likely to result from public disclosure justifies a claim for confidentiality, NDSAC may,

(a) order that the document not be placed on the public record; or

(b) order disclosure of an abridged version of the document.

Attendance of Witnesses

16. (1) NDSAC may request the attendance of any person that NDSAC believes to have information relevant to the proceeding.

Hearing

17. (1) Witnesses at a hearing shall be examined viva voce on oath unless otherwise provided by these Rules, and for this purpose, NDSAC may require a commissioner of oaths to swear in witnesses.

(2) NDSAC may, at any time, order that,

(a) any particular facts be proved by affidavit;

(b) the affidavit of any witness be read at a hearing on such conditions as NDSAC thinks reasonable; and

(c) any witness be examined before a person authorized to take evidence under oath.

(3) Where memoranda of evidence have been furnished prior to the commencement of a hearing, NDSAC may permit the introduction of those memoranda as evidence in chief by a witness who,

(a) testifies as to his qualifications; and

(b) confirms that the memoranda were prepared under his direction or control and are accurate to the best of his knowledge and belief.

Examination

18. (1) NDSAC may require any witness to attend before a person authorized to take evidence under oath for an examination.

(2) The evidence taken by a person referred to in subsection (1) shall be confined to the subject-matter in question and any objection to the admission of evidence shall be noted and dealt with by NDSAC at the hearing.

(3) Such notice of the time and place of examination as is prescribed in an order under subsection (1) shall be given to the parties required to attend.

(4) All examinations shall be returned to NDSAC and the depositions certified under the hand of the person taking them may without further proof be used in evidence, saving all just exceptions.

(5) NDSAC may order further evidence to be given viva voce or by depositions taken before a person authorized to take evidence under oath appointed by it for that purpose.

Sittings

19. (1) When a hearing is commenced, it shall proceed, as far as may be practicable in the opinion of NDSAC, from day to day.

(2) NDSAC may hold more than one sitting at the same time, and whenever circumstances render it expedient to hold a sitting elsewhere than in the National Capital Region, NDSAC may hold the sitting in any part of Canada.

Argument

20. NDSAC may, whenever it deems it advisable to do so, order written briefs to be submitted by the parties in addition to or in lieu of oral argument

Adjournment

21. NDSAC may, at any time, adjourn any proceeding before it.

Defects in Form

22. No proceeding shall be defeated by any objections based solely on defects in form.

Amendments

23. NDSAC may, on terms or otherwise,

(a) make or allow any amendments in any proceeding, or

(b) order to be amended or struck out any matters that, in the opinion of NDSAC, may tend to prejudice, embarrass or delay a fair hearing of the proceeding on the merits.

Dispensing with Procedure

24. In respect of any proceeding, NDSAC may, where appropriate, dispense with, vary or supplement any of the provisions of these Rules.

PART II – PROCEDURE IN DRUG SCHEDULING REVIEW

25. Unless otherwise determined by NDSAC, the procedure in a proceeding shall typically follow the following format,

(a) NDSAC shall receive an application for a drug scheduling review from NAPRA;

(b) NDSAC shall determine whether or not the application should proceed, and if not shall communicate this matter to NAPRA forthwith and the balance of this section does not apply;

(c) If NDSAC allows the application to proceed and the applicant is not the manufacturer of the drug to which the application relates, the applicant shall be granted standing as an interested party;

(d) NDSAC shall provide a copy of the application or require that the applicant provide a copy to each such party, which may, in the opinion of NDSAC, have an interest in the application, and shall provide each such party a reasonable opportunity to request standing as an interested party;

(e) Once NDSAC has ruled on who will be granted standing as an interested party in the proceeding, it shall circulate a list of such parties with contact information to all parties, and shall require that any materials that have been or are filed in the proceeding by any interested party be served on every other interested party promptly;

(f) NDSAC may, if it considers appropriate, pose interrogatories to the manufacturer of the drug or to an applicant who is not the manufacturer of the drug and may grant interested parties an opportunity to pose interrogatories to the manufacturer of the drug and/or to an applicant who is not the manufacturer of the drug, and in such an event shall specify when responses to interrogatories are due, and when and how any procedural matters relating to such interrogatory response may be addressed;

(g) NDSAC may, if it considers appropriate, allow interested parties other than the manufacturer of the drug or applicant who is not the manufacturer of the drug an opportunity to file evidence concerning the factors relevant to the scheduling of the drug as set out in the Manual;

(h) NDSAC may, if it considers appropriate, allow interested parties an opportunity to pose interrogatories to any interested party described in (g), and in such an event shall specify when responses to interrogatories are due, and when and how any procedural matters relating to such interrogatory response may be addressed;

(i) NDSAC shall hold an oral hearing at which the manufacturer of the drug and any party filing evidence in the proceeding may be required to provide oral evidence and to be available for examination by NDSAC;

(j) NDSAC may, if it considers appropriate, permit interested parties to make representations regarding any issues raised by questions asked under clause (i) above and receive additional written submissions subsequent to the conclusion of the hearing;

(k) NDSAC shall make a proposed recommendation to NAPRA, and shall provide a copy to every interested party.

26. NDSAC may, on application or on its own motion, review and vary or confirm any ruling made under these Rules.

PART III - FORMS

FORM 1

Response to Interrogatory

(full name of party furnishing response)
(date of response)

Response to Interrogatory
Name 1(Name2)01Aug99-100
Page 1 of 1

Q. *(reproduce original interrogatory)*

A. (set out response)