

NATIONAL ASSOCIATION OF PHARMACY REGULATORY AUTHORITIES

BYLAW NO. 2

PART I - INTERPRETATION

1. This Bylaw may be cited as the NAPRA Drug Scheduling Procedural Bylaw.
2. (1) In this Bylaw and in the Rules,

"Act" means the *Canada Not-for-profit Corporations Act (S.C. 2009, c. 23)*, as amended from time to time and every statute that may be substituted therefor and, in the case of each such substitution, any references in this Bylaw to provisions of the Act shall be read as references to the substituted provisions therefor in the new statute or statutes;

"Bylaw" means a bylaw of NAPRA as amended from time to time;

"drug" has the meaning set out in the *Food and Drugs Act, R.S.C. 1985, c. F-17*, as amended from time to time;

"drug scheduling" or "scheduling" means listing in a Schedule;

"Drug Scheduling Register" means a register maintained by NAPRA listing parties that seek notification of drug scheduling reviews (e.g. the Drug Scheduling External Liaison Group);

"drug scheduling review" means a proceeding held to establish or review the scheduling of a drug;

"Board of Directors" has the meaning set out in NAPRA's corporate Bylaws;

"final recommendation" means a Scheduling recommendation made by the Board of Directors;

"interested party" means the manufacturer of a drug subject to a drug scheduling review or any person, association or other entity that, in the opinion of NDSAC, has or represents a significant interest in the scheduling of a drug other than the manufacturer of the drug;

"Letters Patent" means the original letters patent and any supplementary letters patent of NAPRA;

"Manual" means the manual published electronically by the National Association of Pharmacy Regulatory Authorities entitled "Canada's National Drug Scheduling System", dated September 25, 1998, as that manual is amended from time to time;

"manufacturer of a drug" includes the Canadian agent of a non-Canadian manufacturer of a drug;

"member" means a member of NDSAC;

"NAPRA" means the National Association of Pharmacy Regulatory Authorities, a Canadian non-share capital corporation incorporated under the Act;

"NDSAC" means the National Drug Scheduling Advisory Committee of NAPRA;

"proposed recommendation" means a Scheduling recommendation made by NDSAC to NAPRA;

"reassessment" means a hearing carried out pursuant to section 8;

"Rules" means the *Rules of Procedure of the National Drug Scheduling Advisory Committee in Regard to Drug Scheduling Proceedings* established by NAPRA pursuant to this Bylaw;

"Secretary" means the Executive Director of NAPRA or his/her delegate; and

"Schedule" means a schedule contained in the Manual that is used to classify drugs for the purpose of recommending the manner in which the public is granted access to the drugs listed therein.

(2) The provisions of the *Interpretation Act*, R.S.C. 1985, c. I-21, as amended from time to time, apply to this Bylaw *mutatis mutandis*.

PART II – DRUG SCHEDULING

3. A drug that is lawfully sold to the public prior to being scheduled shall be deemed to be listed in Schedule I until such time as a final recommendation has been made, and this requirement shall be included in the Manual.
4. (1) A drug scheduling review may be commenced by NAPRA in its discretion, upon request by a manufacturer of a drug when the drug has not previously been scheduled, provided that the manufacturer of the drug pays the required application fee and provides a written undertaking agreeing to adhere to this Bylaw No. 2 and to the Rules.

(2) A drug scheduling review may be commenced by NAPRA in its discretion, upon request by a manufacturer of a drug when the drug has previously been scheduled, provided that the manufacturer of the drug pays the required application fee and provides a written undertaking agreeing to adhere to this Bylaw No. 2 and to the Rules.

(3) A drug scheduling review may be commenced by NAPRA upon request by an interested party if NAPRA deems that a review is in the public interest provided that the interested party pays the required application fee and provides a written undertaking agreeing to adhere to this Bylaw No. 2 and to the Rules.

(4) A drug scheduling review may be commenced at any time by NAPRA, on its own motion, or upon request from NDSAC, if NAPRA deems that a review is in the public interest, whether or not the drug has previously been scheduled.
5. (1) Upon commencing a review for the purpose of scheduling a drug, NAPRA shall initially refer the matter to NDSAC, which may, subject to the Rules, provide interested parties with an opportunity to be heard and then make a proposed recommendation.

(2) Every proposed recommendation made by NDSAC shall be published in writing and shall be supported by written reasons, but for greater certainty, where the exigency of the situation so requires, NDSAC may publish a proposed recommendation with written reasons to follow.

(3) The Secretary shall forward a true copy of every proposed recommendation and supporting written reasons therefor to the Board of Directors members within seven days of publication.

- (4) In order to provide interested parties the opportunity to be heard upon either the commencement of a review for the purpose of the scheduling of a drug as contemplated by subsection 5(1) or the commencement of a reassessment as contemplated by subsection 8(1), NAPRA shall publish on its website a notice of each such review or reassessment, as soon as practicable after the commencement of the review or reassessment.
6. NDSAC may require any interested party to submit to NDSAC, in such form and manner as NDSAC specifies, any information that NDSAC considers necessary in the course of a drug scheduling review.
7. (1) Subject to section 8, at any time within fifteen (15) days following the 30-day period referred to in section 8(1) below, the Board of Directors may, without any further hearing, publish a final recommendation confirming or rejecting the proposed recommendation or require that a reassessment be conducted. The final recommendation shall be supported by written reasons, but for greater certainty, where the exigency of the situation so requires, the Board of Directors may publish the final recommendation with written reasons to follow.
- (2) Subject to section 8 and in the absence of the publication of a final recommendation within the timeframe specified in subsection (1), the proposed recommendation shall be deemed to have been confirmed as a final recommendation and shall have the same force and effect as a final recommendation that is published by the Board of Directors.
- (3) The Manual shall be updated concurrently with any scheduling change resulting from a final recommendation.
8. (1) An interested party may request a reassessment by NDSAC within 30 days after the publication of the proposed recommendation referred to in section 5(2) above, by notice in writing delivered to the Secretary and NDSAC may, in its discretion, permit a reassessment where it deems that a reassessment would be in the public interest.
- (2) The provisions contained in this Bylaw and the Rules applicable to drug scheduling reviews shall apply to a reassessment.
- (3) Following a reassessment, NDSAC shall make a finding confirming or varying the proposed recommendation in respect of which the reassessment was conducted, in such manner as NDSAC deems appropriate. Such a finding, once made, shall be treated as a proposed recommendation.
- (4) The Board of Directors shall not make a final recommendation in respect of a proposed recommendation that is subject to a reassessment that has commenced pursuant to subsection (1) and not yet resulted in a finding described in subsection (3).
- (5) NDSAC may not commence a reassessment of a proposed recommendation where NAPRA has commenced deliberations concerning the proposed recommendation or has published or been deemed to have published a final recommendation to the proposed recommendation.

PART III – ADMINISTRATION

9. The Board of Directors has final authority in drug scheduling matters, and, without limitation, is authorized,
- 1) to approve final recommendations;
 - 2) to maintain and publish the Manual;
 - 3) to oversee and co-ordinate the activities of NDSAC;

- 4) to require NDSAC to make a report on any matter relating to drug scheduling falling within NAPRA's jurisdiction;
- 5) to make rules governing the practices and procedures of NAPRA and NDSAC (including, without limitation, the establishment of fees);
- 6) to take such other actions as it considers proper to give effect to its drug scheduling mandate.

NDSAC is authorized,

- 1) to hear drug scheduling applications;
 - 2) to make proposed recommendations;
 - 3) to make a report on any matter within NAPRA's jurisdiction in accordance with a request from NAPRA; and
 - 4) to make recommendations to NAPRA regarding matters falling within the drug scheduling mandate given to NAPRA, as amended or revised from time to time.
10. NAPRA and NDSAC shall at all times exercise its powers and perform its duties in relation to drug scheduling,
- (A) in accordance with the Act, the Letters Patent, the Bylaws, and the Rules; and
 - (B) in a manner that promotes,
 - (i) the harmonization of the conditions of the sale of drugs throughout Canada; and
 - (ii) the efficiency and effectiveness of the drug scheduling process
11. (1) NAPRA may establish and revise from time to time a schedule of application fees payable by manufacturers of drugs or by interested parties under various specified circumstances when requesting a drug scheduling review.
- (2) The fees established and revised from time to time pursuant to subsection (1) shall be based on the estimated costs, both direct and indirect, of conducting drug scheduling reviews including, without limitation, the costs relating to providing ongoing administrative and other support services.
12. (1) NDSAC may implement a Drug Scheduling Register and may add or delete parties to and from the Drug Scheduling Register upon request or as it may, in its discretion, determine.
- (2) Any person or association may request to be added to or deleted from the Drug Scheduling Register by submitting a written request to that effect to the Secretary and may provide up-to-date contact information to the Secretary from time to time.
- (3) NAPRA may from time to time send inquiries to persons or associations whose names appear on the Drug Scheduling Register to verify whether or not their names should be maintained on the register, or whether their contact information is correct.
13. (1) The manufacturer of a drug has standing before NDSAC in a drug scheduling review relating to its own drug.

- (2) Subject to subsection (1), only a party designated as an interested party by NDSAC shall have standing in a drug scheduling review and the decision of NDSAC that a person is or is not an interested person in a particular drug scheduling review is binding and conclusive.
14. For the purposes of a drug scheduling review, a quorum of NDSAC consists of five members.
 15. For the purposes of a drug scheduling review, a quorum of the Board of Directors consists of fifty percent plus one (50%+1) of the members.
 16. NAPRA may extend the period, whether fixed by the Rules or otherwise, for doing anything required to be done in proceedings before it.
 17. In conducting drug scheduling reviews, NDSAC may require,
 - (A) the attendance and examination of witnesses under oath; and
 - (B) the production and examination of any document, information or thing.
 18. The *Canada Evidence Act*, R.S.C., 1985, c. C-5, as amended from time to time, applies to drug scheduling reviews.
 19. The Board of Directors may, on application or on its own motion, review and vary or confirm any final recommendation or re-hear a matter before rendering a final recommendation.
 20. NAPRA hereby adopts the *Rules of Procedure for the National Drug Scheduling Advisory Committee in Regard to Drug Scheduling Proceedings* attached as the Schedule to this Bylaw.