



Application for Drug Scheduling

SAMPLE TEMPLATE

NAPRA | NDSAC

This document is intended to assist in the preparation of scheduling applications and 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 By-law or Rules of Procedure and this document, the provisions of the Rules of Procedure or By-law, as applicable, shall prevail. Questions related to drug scheduling applications should be directed to the NDSAC secretariat at ndsac@napra.ca

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1. Statement of the Requested Schedule Recommendation

1.1 INTRODUCTION

This section can be a general overview/summary of the drug scheduling application.

1.2 STATEMENT OF THE REQUESTED SCHEDULE RECOMMENDATION

This section must indicate which schedule is being requested by the applicant for the drug to be reviewed.

e.g. Company ABC is requesting Schedule XX status for Drug123.

A short paragraph summarizing the rationale for this request is generally included.

An outline of the schedules and categories of the National Drug Schedules (I, II, III and Unscheduled) can be found on the NAPRA website:

<https://napra.ca/sites/default/files/documents/Schedules-Outline.pdf>

2. Drug Overview

This section must include a written summary that contains information on the conditions for use, safety and efficacy, a description and incidence of adverse reactions, and experience with overdose if relevant.

2.1 INDICATIONS AND CONDITIONS FOR USE

This section must include information on the conditions for use and Health Canada approved indications.

2.2 DOSAGE AND ROUTE OF ADMINISTRATION

This section must review dosage (including maximum daily doses) and route of administration details.

2.3 MECHANISM OF ACTION / PHARMACOKINETICS

This section must describe the mechanism of action and relevant pharmacokinetic parameters (such as absorption, distribution, metabolism, and elimination).

2.4 SAFETY AND EFFICACY

This section must include information about safety and efficacy from clinical trials, as well as any available post-market information.

2.5 ADVERSE REACTIONS

This section must include information about adverse reactions from clinical trials, as well as any available post-market information.

2.6 OVERDOSE

If available, this section must include any overdose information (concerns, risks, treatments, etc.).

3. Application of the Scheduling Factors

This section of the submission must include the rationale for whether or not each of the NDS scheduling factors applies to the drug, which should then tie into the rationale for the specific schedule request (II, III or Unscheduled). In keeping with the cascading principle of drug scheduling, an application of the scheduling factors for all of the schedules must be included, in support of the scheduling request. The National Drug Scheduling Factors can be found on our website. For each factor, please indicate whether or not the factor applies with rationale and include appropriate supporting references with literature citations. Many companies also include a summary paragraph at the end that explains why the particular schedule is requested, based on the application of the scheduling factors.

SCHEDULE I FACTORS

#1 The need for the drug is identifiable only by the prescribing practitioner.

Applicable OR Not Applicable + rationale that includes literature citations

#2 Use of the drug requires adjunctive therapy or evaluation.

Applicable OR Not Applicable + rationale that includes literature citations

#3 Appropriate use of the drug may produce dependency.

Applicable OR Not Applicable + rationale that includes literature citations

#4 Serious adverse drug reactions are known to occur or have a recognized potential to occur at normal therapeutic dosage levels.

Applicable OR Not Applicable + rationale that includes literature citations

#5 There is a narrow margin of safety between the therapeutic and toxic dosages of the drug, either in the general population or in identified subpopulations, or in patients with multiple medical problems.

Applicable OR Not Applicable + rationale that includes literature citations

#6 Serious drug interactions are known to occur.

Applicable OR Not Applicable + rationale that includes literature citations

#7 Use of the drug has contributed to, or is likely to contribute to, the development of resistant strains of microorganisms.

Applicable OR Not Applicable + rationale that includes literature citations

#8 The medicinal ingredient is new, or is being used for a new indication that is not amenable to self-treatment, and the consequences of widespread use are not adequately established.

Applicable OR Not Applicable + rationale that includes literature citations

SCHEDULE II FACTORS

#1 The initial need for the drug is identified or confirmed by a regulated health professional.

Applicable OR Not Applicable + rationale that includes literature citations

#2 Chronic therapy or subsequent re-treatments should be monitored by a pharmacist.

Applicable OR Not Applicable + rationale that includes literature citations

#3 The drug must be readily available under exceptional circumstances when a prescription is not practical.

Applicable OR Not Applicable + rationale that includes literature citations

#4 The drug is intended for administration in a health care setting or under the direction of a regulated health professional, or is an injectable dosage form and is not otherwise included in Schedule I.

Applicable OR Not Applicable + rationale that includes literature citations

#5 There is significant potential for misuse or abuse of the drug, due to its inherent pharmacological action or chemical properties.

Applicable OR Not Applicable + rationale that includes literature citations

#6 The selection of the drug requires intervention by a pharmacist:

- to confirm that an appropriate self-assessment has been made by the patient; or*
- for a condition that is new to patient self-assessment; or*
- for a condition that is generally not amenable to patient self-assessment.*

Applicable OR Not Applicable + rationale that includes literature citations

#7 Use of the drug may delay recognition or mask the symptoms of serious disease.

Applicable OR Not Applicable + rationale that includes literature citations

#8 The drug may cause serious or significant adverse drug reactions or drug interactions that cannot be adequately addressed through product labeling.

Applicable OR Not Applicable + rationale that includes literature citations

#9 Safe and appropriate use of the drug requires intervention by a pharmacist to reinforce or expand on limited, or complex, information that appears on product labeling.

Applicable OR Not Applicable + rationale that includes literature citations

#10 The medicinal ingredient is new or is in a new drug delivery system, for self-medication.

Applicable OR Not Applicable + rationale that includes literature citations

SCHEDULE III FACTORS

#1 Chronic use may delay recognition or mask the symptoms of serious disease.

Applicable OR Not Applicable + rationale that includes literature citations

#2 The drug is a new ingredient for self-selected self-medication and the availability of a pharmacist to provide advice can promote appropriate use.

Applicable OR Not Applicable + rationale that includes literature citations

#3 The drug is used to treat a persistent, chronic or recurring condition and the availability of the pharmacist to provide advice can promote appropriate use.

Applicable OR Not Applicable + rationale that includes literature citations

#4 There is potential for misuse or abuse of the drug, due to its inherent pharmacological action or chemical properties.

Applicable OR Not Applicable + rationale that includes literature citations

#5 The availability of a pharmacist to reinforce or expand on product labeling, or where product selection is likely to cause confusion, could contribute to the safe and appropriate use of the drug

Applicable OR Not Applicable + rationale that includes literature citations

4. Product Labelling

4.1 PACKAGE LABELS

This section must include inner and outer package labels that are identified with titles that clearly outline what is represented (for example, “30-count outer label”). If available, include both mock-ups and text-only versions.

4.2 APPROVED HEALTH CANADA PRODUCT MONOGRAPH

This section must include the final Health Canada approved product monograph, including the patient information section (Part III).

5. Consumer Usage Studies

This section must include results of consumer usage studies in a market consistent with the scheduling request regarding compliance and related issues, such as reading and comprehension studies of labels and patient information.

5.1 LABEL COMPREHENSION STUDIES

Please provide any label comprehension studies that used the current, Health Canada approved labelling. If not available, please provide a statement indicating why label comprehension studies with the current, Health Canada approved labels were not completed. Label comprehension studies completed in other jurisdictions can be provided if the labelling is the same or very similar.

5.2 ACTUAL USE STUDIES

Please include any available studies that address patient compliance or real-world usage. If not available, please provide a statement indicating why actual use studies were not completed.

6. Drug Status in Other Countries

This section must include a list of the countries in which the drug is approved and the current status of the drug in those countries (such as prescription only, pharmacy only, any retail outlet).

7. Exposure Assessment / Market Penetration

This section must include information on the number of individuals that have been exposed to the drug. The information provided usually includes population exposure to the drug product (for example, how many people have used the product since its launch, both in Canada and throughout the world).

8. Health Canada Reviewer's Report

This section must be included if the drug scheduling request is pursuant to a deregulatory proposal (prescription to non-prescription-switch). Applicants are encouraged to include the Health Canada reviewer's report for non-switch drug products. Please include a summary of the background information used and evaluation prepared by the Health Canada reviewers.

9. References

9.1 LITERATURE SEARCH PARAMETERS

This section must include the literature search parameters used to complete the application of the scheduling factors.

As an example, the following information is usually provided:

- Search title: What information are you looking for
- Searched Databases: Which databases you used to complete your search (ex. Medline)
- Search Date: When did you complete your search
- Publication dates: What dates of publication did you include (ex. Cumulative until Month XX, 20XX)
- Search Strategy: What terms did you use to search (ex. Drug123 safety, Condition A, Drug123 Brand name etc.)
- Results: How many references were retrieved and if they were applicable to your application of the scheduling factors

9.2 LIST OF REFERENCES

This section must include a list of all references that are cited in the submission, either in order of appearance or in alphabetic order. You may choose the referencing style that you prefer, as long as it is consistent.

9.3 COPIES OF ALL REFERENCES CITED IN THE SUBMISSION

This section must include a PDF copy of each of the references cited in the submission. They may be appended to the submission, or provided separately. If a reference is not available or is extremely long, please contact the NDSAC secretariat to discuss how to handle this well in advance of the submission deadline (ndsac@napra.ca).