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

External Consultation: Phase 1B
National Drug Schedules (NDS) Modernization Project
Determining the appropriate NDS model for the future

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Preamble

The National Association of Pharmacy Regulatory Authorities (NAPRA) is currently in the process of facilitating a multi-phase, multi-year project to review the National Drug Schedules (NDS) program. Starting in 2011, NAPRA began conducting several review activities to inform this project, including the completion of surveys, research projects, legal analysis and obtaining member and external organization input about the program.

In 2019, the NAPRA Board of Directors met to discuss the compilation of data and to determine the next steps. The Board decided to move forward with modernizing the NDS program, with a focus on the future needs, the public and patient lens, and role of other health professions. Subsequently, an NDS Modernization Roadmap was developed and was approved in November 2021.

Overall, the objective of the NDS Modernization Project is to develop a new, modernized NDS program that best meets the needs of the healthcare system now and into the future, while applying learnings from NAPRA's experience with the program over the last 29 years. NAPRA will be seeking external feedback throughout the course of this project. The project will include four phases of 1) Conceptualization and Modelling 2) Funding and Authority 3) Policies and Processes, and 4) Implementation. The phases will be worked on sequentially, with each one dependent on the outcomes of the phases that come before.

Phase 1 is the Conceptualization and Modelling phase and is comprised of two parts. Phase 1A was completed in summer 2023 with the outcome of:

1. creating a list of **future trends** in healthcare and pharmacy practice to inform the rest of the project,
2. determining what success would look like for the process of modernizing the NDS program by outlining how to achieve **success**, and
3. establishing a set of **guiding principles** for a modern NDS program.

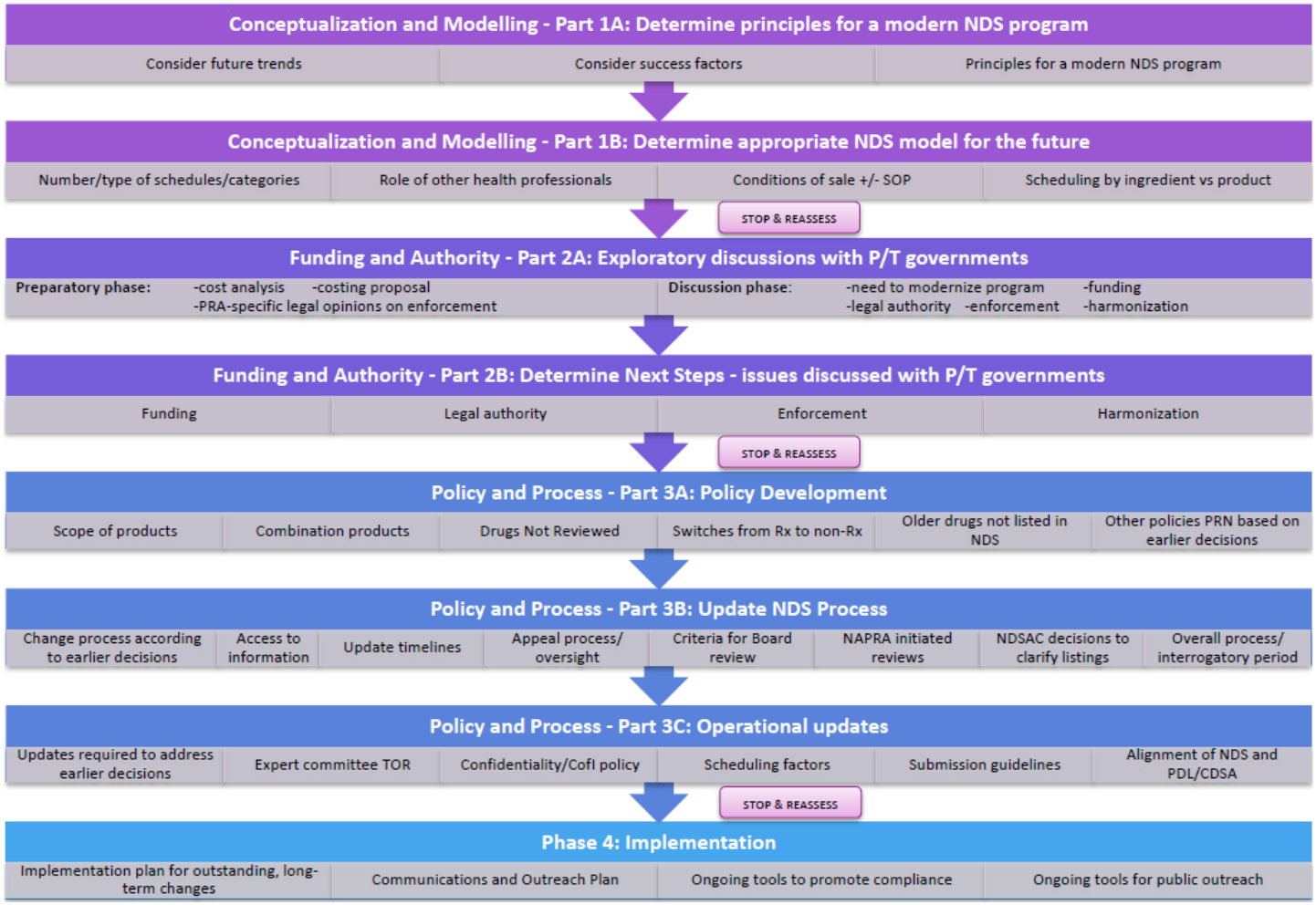
Work on Phase 1B commenced following the completion of phase 1A with the objective of determining the most appropriate drug scheduling model for the future, including conditions of sale. The core elements to confirm at this stage of the project include:

1. Addressing two preliminary questions for the NDS program structure:
   - Should the modernized model schedule by ingredient or by product?
   - Should the modernized model have a prescription-only category?
2. Confirming which scheduling model is most appropriate for a modernized NDS program, and
3. Determining the conditions of sale to accompany the modernized scheduling model.

Further details on this phase along with future phases of the NDS Modernization Project are outlined in the roadmap image found below.

NDS Modernization Roadmap

[1]



[1] CDSA = controlled drugs and substances act
PRN = Latin term pro re nata, meaning as needed
SOP = Standards of practice
CofI = Conflict of interest
PDL = prescription drug list
TOR = terms of reference
PRA = pharmacy regulatory authority
Rx = prescription

Phase 1B Background Information

Current NDS model

The NDS scheduling model that is in place presently, and has been in place since 1995, consists of three schedules and four categories of drugs.

Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. The sale is controlled in a regulated environment as defined by provincial pharmacy legislation.

Schedule II drugs, while less strictly regulated, do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection.

Schedule III drugs may present risks to certain populations in self-selection. Although available without a prescription, these drugs are to be sold from the self-selection area of the pharmacy which is operated under the direct supervision of the pharmacist, subject to any local professional discretionary requirements which may increase the degree of control. Such an environment is accessible to the patient and clearly identified as the "professional services area" of the pharmacy. The pharmacist is available, accessible, and approachable to assist the patient in making an appropriate self-medication selection.

Unscheduled drugs can be sold without professional supervision. Adequate information is available for the patient to make a safe and effective choice and labeling is deemed sufficient to ensure the appropriate use of the drug. These drugs are not included in Schedules I, II or III and may be sold from any retail outlet.

Details on the existing program can be found on the NAPRA website.

Approach to modernizing the NDS model

It is anticipated that the outcomes of Phase 1B will have a significant impact on each of NAPRA's members as well as the public and many other organizations and interested parties whose work relates to non-prescription drugs (NPDs). As such, NAPRA recognizes that this phase of the project requires significant research and robust engagement to gather as much information and feedback as possible to support the decision-making process.

Preliminary work was conducted to gather the available literature and information about drug scheduling in other jurisdictions to help inform the conversations and consultation. Background information was also found on the value of drug scheduling in Canada and around the world and the value of, as well as the limitations with, product labelling. Additionally, the views from other regulated health professionals on the NDS program were gathered. Lastly, details on how scheduling can be organized were summarized to help confirm if the modernized structure should continue scheduling by

ingredient or if there was value in changing the structure to consider scheduling by product. A summary of this background information is available in Appendix 1.

In addition to the research and environmental scanning, prior to this external consultation process, preliminary consultation was held through engagement with a Pharmacy Regulatory Authorities (PRA) Working Group (WG) and a Multi-Sector Advisory Table (MSAT). The PRA WG is composed of a regulatory authority representative from the following jurisdictions: British Columbia, Saskatchewan, Manitoba, Ontario, Quebec, Nova Scotia, and Newfoundland & Labrador. MSAT members include academic/researchers with expertise in NPDs, current and past members of the National Drug Scheduling Advisory Committee (NDSAC), industry representation, patient/public representation, medical expertise, federal government representation, and association representatives from the Canadian Pharmacists Association, Indigenous Pharmacy Professionals of Canada, Canadian Society of Hospital Pharmacists, and Canadian Association of Pharmacy Technicians.

Meetings were held separately with these groups to gather input on a variety of scheduling models for consideration and to validate proposed recommendations based on the available research and resources. Each group was kept informed of the conversations held with the other. In total, three meetings were held with the PRA WG and two meetings were held with MSAT from November 2023 to March 2024.

All the research and reports generated were shared with each member of the PRA WG and MSAT for review to help inform their feedback. Members of these groups were asked for their input on the two preliminary questions related to the structure of the NDS model as well as to provide their perspective on different scheduling options that could be considered for a modernized approach.

Based on the advice and input from these two advisory groups, this consultation document has been created to continue gathering broader and more robust feedback from a larger group of interested parties to help inform the decision-making process in determining what the modernized NDS model should look like. As outlined above, feedback is being sought under three main headings: preliminary questions, the scheduling model, and conditions of sale.

Review of Preliminary Questions

To support the implementation of a modernized NDS program, two important preliminary questions arose for validation. These questions are:

1. Should the modernized model schedule by ingredient or by product?
2. Should the modernized model have a prescription-only category?

The path forward regarding both questions will need to be determined in conjunction with determining the modernized scheduling model and the updated conditions of sale. The NDS Modernization Project is a multi-phase, multi-year project and given the broad scope of the project, it is recognized that everything is interrelated. Factoring in the decisions made on these two questions will be imperative to confirming the other pieces in this phase as well as factoring these decisions into the work in future phases of the project.

Below are summaries and background information on each of the questions.

Background – Question 1: Should the modernized model schedule by ingredient or by product?

After reviewing the information available related to the pros and cons of scheduling by ingredient versus by product it was found that there was minimal direct evidence on this topic to clearly state one approach was significantly safer or more effective than the other. Based on the assessment of some pros and cons for each of the approaches, it was determined that there appear to be more benefits and fewer disadvantages to scheduling by ingredient versus by product.

The Prescription Drug List and schedules to the *Controlled Drugs and Substances Act* and its regulations maintained by Health Canada are listed by ingredient. Misalignment with these federal lists is a fairly significant con that could result in a lot of confusion were the NDS to move to scheduling by product. Scheduling by product could result in an overwhelming amount of work that ends up being very duplicative and not justifiable from a public health point of view, since there would be little difference between products with the same ingredients. The main disadvantages of scheduling by ingredient relate to the fact that labelling can be different between products with the same ingredients and to the unequal costs for market authorization holders, with one company paying for a review that would benefit other manufacturers of the same ingredient. These issues, however, could be addressed via policies and procedures related to labelling and a revised funding model, which are all elements of consideration in future phases of this project.

It was also noted that scheduling by ingredient may potentially be less user friendly. However, the target audience for the NDS is health professionals, who have the training to be able to identify the ingredients in a particular product to use a database organized by ingredient, thus this negative was considered to have a minimal impact. The risk of non-medicinal ingredients in different product versions significantly influencing the benefit-risk profile of an active ingredient is considered to be rare. This was not considered a strong enough rationale for switching to scheduling by product, given the other factors assessed, but it was later determined that there should be a mechanism to make exceptions for such rare cases.

Throughout the discussions with the PRA WG and MSAT, it was determined that scheduling by ingredient continues to be the most appropriate approach, but that there should be the potential for exceptions in certain circumstances. Exceptions would allow for flexibility in the program should innovation introduce other elements beyond the active drug ingredient that modify its safety and efficacy (e.g., non-medicinal components, dosage forms, etc.). The current program already does this to some extent, with some NDS listings being specific to a certain dose, dosage form or indication or use. This suggestion was agreed upon by participants in both the PRA WG and MSAT as a useful caveat to be included in the final recommendation.

Therefore, it is recommended that the NDS continue to schedule by ingredient, with provisions to allow exceptions to be made based on specific circumstances (e.g., specific elements beyond the ingredient itself that affect safety and efficacy).

If there is support for this approach, a policy would be created in future phases of the project to clarify when and how such exceptions would be made.

Background – Question 2: Should the modernized model have a prescription-only category?

There have been suggestions that removing a prescription category could improve nimbleness and timeliness of the NDS process and could potentially save on resources. In a 2011 NAPRA report prepared by Peter Cameron and Associates, most participants in the survey were supportive of the current scheduling model, but there were some suggestions to consider placing drugs in Schedule II by default instead of in Schedule I by default.[2] It was suggested that this could improve the process, as non-prescription access would be automatically in place, with pharmacist intervention as a safeguard. Placing drugs in a pharmacist intervention category for a certain amount of time was also felt to potentially save on resources, by not initiating a review until there was more real-world data on non-prescription use of the drug in Canada.

There have also been questions about the value-add of maintaining a prescription category, since a pharmacist (or other authorized health professional) intervention category could provide similar controls. The health professional would need to complete a patient assessment and only provide the drug if it is safe and appropriate for the patient, just as they would prior to prescribing. The only difference would be that a prescription would not necessarily need to be written out on a piece of paper.

Although not as significant an issue, the existence of Schedule I causes confusion about the role of NAPRA versus Health Canada in the drug scheduling process. The existence of Schedule I is often interpreted as meaning that NAPRA determines which drugs require a prescription, when in fact this is a Health Canada role, with NAPRA only adding additional requirements for a small sub-set of ingredients.

Overall, removal of a prescription category may improve nimbleness/timeliness of the program, may save on resources, and could help to clarify the role of NAPRA versus Health Canada, without any undue effects on patient safety, since a health professional would still complete the same assessment and only provide the drug if it is safe and appropriate for the patient.

The discussions with the PRA WG and MSAT confirmed that, given the pros and cons that have been outlined, not maintaining a prescription only category would be appropriate for a modernized NDS program, as long as there was a mechanism to ensure pharmacist (or other health professional) intervention for certain drugs.

Therefore, it is recommended that NAPRA not maintain a separate prescription category, as long as a pharmacist (or other authorized health professional) intervention category is maintained.

Consultation input – preliminary questions

Based on the information presented above, NAPRA is seeking feedback from all interested parties on the following two recommendations.

Recommendation 1: that the NDS continue to schedule by ingredient, with provisions to allow exceptions to be made based on specific circumstances (e.g., specific elements beyond the ingredient itself that affect safety and efficacy).

[2] Peter Cameron & Associates Inc. Background document to support the review of the National Drug Schedules program. Prepared for the National Association of Pharmacy Regulatory Authorities. November 2011.

Recommendation 2: that NAPRA not maintain a separate prescription category, as long as a pharmacist (or other authorized health professional) intervention category is maintained.

Directions on how to provide your feedback can be found in the Consultation Feedback section of this report.

Review of Scheduling Options

Background – Scheduling Options

Different jurisdictions around the world employ different drug scheduling structures to control the sale of non-prescription drugs (NPDs). For example, the United States (U.S.) does not place any scheduled restrictions on the sale of NPDs. Simply put, in the U.S., NPDs fall under the general sales category and are not further classified into schedules. Most other similar countries to Canada do implement additional controls on the sale of NPDs. The United Kingdom (U.K.) implements a two-tiered system where NPDs are categorized as either under the control of a pharmacist in a pharmacy or available in a general sales category[3]. Australia's system is like the one in place presently in Canada, which includes a pharmacist-only category, pharmacy-only category, and a general sales category[4].

Since these systems were implemented, both the U.S. and Australia have conducted reviews on the program they have in place. No new evidence was found during the U.S. (1995, 2009) and Australia (2001, 2005) reviews of their drug scheduling systems. In these cases, the decision was made to maintain the status quo for their respective systems in the absence of evidence-based rationale for change. Of note, in the 2005 Australian review, evidence was found that pharmacist interventions had an impact on health benefits and avoidance of healthcare costs, but concluded the benefit of this interaction was marginal. Also in Australia, a 2013 Pharmaceutical Guild submission to government highlighted that their current drug scheduling system was in the best interest of the public, citing concerns with low-health literacy, vulnerable populations, potential harms of NPDs, and high prevalence of polypharmacy. The European Union also found insufficient evidence to recommend one drug scheduling system over another, which is the reason they do not require a particular system.

Overall, there is no direct evidence proving that one drug scheduling structure or system is better than another. Thus, the value of any one particular drug scheduling system over another is mainly based on perceptions and opinions. Each structure, as seen in many jurisdictions, comes with positives and negatives. As a result, it is challenging to definitively conclude that a change in model structure would be an improvement or in the best interest of the public. On the other hand, this also means that there is no evidence that clearly supports the idea that maintaining the existing model is the best way to support the public interest.

[3] The name of the category under pharmacist control in the U.K. is "pharmacy medicines" or "P" medicines. The requirements for sale for this category fit the definition of pharmacist-only rather than pharmacy-only, as defined in Canada. However, unlike in Canada, in the U.K., suitable trained counter assistants may sell a "P" medicine under the supervision of a pharmacist and will ask questions to determine if the customer should be referred for a discussion with the pharmacist (the specific questions to be asked are mandated by the Royal Pharmaceutical Society).
[4] Belanger D, O'Grady T. Review of Schedules II and III. Prepared for the National Association of Pharmacy Regulatory Authorities. December 2018.

Since there is no direct evidence on the superiority of one model over another, the engagement with our advisory groups was crucial in gathering feedback from a diverse pool of experts who were best positioned to share their professional opinions and past working experience to help inform the decision-making process. Following a period of research and review, some of which is briefly summarized in Appendix 1, NAPRA staff originally proposed six different scheduling options for consideration to the PRA WG and MSAT. These were discussed through several meetings and eventually narrowed down to two options. These two options were then refined and additional details and definitions were created to support their inclusion for broader consultation.

Rationale for Options A and B

The original six options included one in which there would not be any additional conditions of sale for non-prescription drugs, like the U.S. model. However, it was clear from the background research and information (summarized in Appendix 1), as well as from the discussions of the expert groups, that there are certain drugs and certain situations in which general sales for all NPDs is not sufficient to ensure their safe and appropriate selection and use. There are some drugs that present more risk of inversion, diversion or integrity problems that require handling by those with the appropriate training and regulatory oversight. There are certain situations or certain populations, including vulnerable populations, in which additional support beyond labelling is required for safe and appropriate selection and use. Therefore, the PRA WG and MSAT agreed that this was not a viable option moving forward.

The other five original options were variations of the two options being presented for consultation, which were refined based on the expert advice of the PRA WG and MSAT. There was consideration of the potential role of another learned intermediary besides the pharmacist, as in countries like Japan, Germany, and Romania. There was discussion about the potential of utilizing pharmacy technicians in such a role. It was determined that, since pharmacy technicians are not currently trained and competent to apply information to a particular patient and complete clinical assessments, such an option would not provide that much benefit to the public. It was noted that the approach to include other authorized health professions described later in this section could always be applied to pharmacy technicians should their training and competencies evolve in the future.

The first option being presented for consultation includes two scheduling categories, while the second includes three scheduling categories. While parallels may be found with some schedules in the current NDS program, specific language was chosen to describe the categories proposed for the modernized program that focuses on the level of support for patients. This aligns with the patient/public focus for the program.

As noted earlier, consideration was also given to the potential role of other health professionals. Depending on the legislation, regulation, or other regulatory requirements in each of the provinces and territories, the existing drug schedules generally limit the sale of NPDs classified into schedule II and III to a pharmacy, either under the direct control of a pharmacist, or in an area of the pharmacy where access to the pharmacist is possible. Engagement with the PRA WG and MSAT, as well as direction from the NAPRA Board of Directors, has confirmed that the majority of those engaged see the potential value that other health professionals could provide regarding access to NPDs within their respective scopes of practice. However, there was uncertainty regarding how this might be operationalized, particularly in terms of integration and enforcement.

Therefore, it is proposed that the modernized structure be designed to not prohibit other regulated health professionals from leveraging their competence and expertise to support their patients with the purchase and use of NPDs within their scope of practice, and to place the responsibility for enabling and enforcing this with the respective health profession regulators. This is being proposed because it would not be within the role or authority of NAPRA and its members to play a role in determining or enforcing the rules for other health professions, but neither would it be appropriate for the NDS to limit the role these health professionals can play when providing patient care.

As such, the structure of the modernized NDS model should broadly categorize NPDs as either requiring intervention from a pharmacist or other authorized health professional prior to sale or in a category where advice is available and accessible from a pharmacist or other authorized health professional, but not required, prior to purchase. It would be up to the regulatory authorities for each of the professions in each of the Canadian jurisdictions to examine their regulatory requirements, determine whether they will make any modifications to allow their registrants the authority to engage in the sale of NPDs listed in the NDS, and to enforce compliance with the general conditions of sale of the NDS, and any additional standards and rules around the sale of NPDs for their profession.

A definition of authorized health professional has been included in the consultation below to explain this high-level approach to the role of other health professionals. If the concept is supported, detailed requirements on how this high-level approach would be operationalized would be developed in future phases of the project.

Further details on the considerations that were discussed regarding the role of other health professionals can be found in Appendix 2.

Consultation input - options

Based on the information discussed to date with the PRA WG and MSAT, NAPRA is now seeking feedback from all interested parties on the following two options for the model for the modernized NDS program.

Options	*Intervention Required Prior to Purchase	*Advice Available and Accessible Prior to Purchase	General Sales
Option A	X		X
Option B	X	X	X

**The intervention or advice noted in each category must be provided by a pharmacist. It may be provided by another authorized health professional only if that ability has been enabled and will be enforced by the regulator of that profession. In all cases, the conditions of sale would need to be followed. Please see the definitions of authorized health professional, available and accessible, as well as the proposed conditions of sale for more details.*

Appendix 2 outlines the many key considerations for both options A and B to highlight their strengths and weaknesses to help further inform the consultation process and to help respondents determine which model structure should be implemented moving forward.

Definitions

The following definitions should be reviewed in conjunction with the table above and Appendix 2 to ensure understanding of the proposed two scheduling options.

Available: means the pharmacist (or other authorized health professional) is physically present in an in-person sales environment and is able to talk to the patient about the drug before it is purchased. If the sale environment is virtual, the pharmacist (or other authorized health professional) can be synchronously reached in real time and is able to talk with the patient about the drug before it is ordered.

Accessible: means the patient is capable of easily speaking with the pharmacist (or other authorized health professional). If in person, the pharmacist (or authorized health professional) is easy to approach and there are no barriers present that reduce the chance of reaching the pharmacist (or other authorized health professional) to converse about the drug prior to purchase. If the environment is virtual, it is easy to follow the prompts to synchronously reach a pharmacist (or other authorized health professional) to converse about the drug prior to purchase.

Authorized Health Professional: For the purposes of the National Drug Schedules program, an authorized health professional is a regulated health professional whose legal scope of practice allows them to assess individuals and recommend NPDs that are listed in the National Drug Schedules. The authorized health professional may only sell NPDs listed in the National Drug Schedules:

i. if they have been authorized to recommend and sell that drug according to the legal scope of practice and other regulatory requirements of their profession, as determined and enforced by the regulatory authority of that profession, and,
ii. in accordance with the conditions of sale of the NDS, to be enforced by the regulatory authority of that profession.

Sell*:* For the purposes of the NDS program, "sell" has the same meaning as in the *Food and Drugs Act*.

Directions on how to provide your feedback can be found in the Consultation Feedback section of this report.

Review of Conditions of Sale

Background – conditions of sale

Conditions of sale are rules that prescribe what is required by the person or business selling the goods or services such as the requirements that are in place to support the safe and appropriate selection and use of those goods or services, in this case the selection and use of non-prescription drugs.

For the purposes of the NDS program, the table below outlines the requirements for pharmacist (or other authorized health professional) involvement in the sale of NPDs.

Consultation input – conditions of sale

To accompany the decision on a modernized scheduling model, NAPRA is seeking feedback from all interested parties on the proposed details outlined for conditions of sale, which would be used in conjunction with the scheduling model of the modernized NDS program. The following table details the proposed conditions of sale for the different categories in the two proposed scheduling options.

Conditions of Sale	Intervention Required Prior to Purchase	Advice Available and Accessible Prior to Purchase	General Sales
Access to the drug	A pharmacist (or other authorized health professional) must intervene to complete an assessment prior to purchase, to determine if the drug is safe and appropriate for the particular individual.	A pharmacist (or other authorized health professional) must be available and accessible to provide advice prior to purchase about safe and appropriate use of the drug for the particular individual.	The drug can be obtained at any location without conditions of sale.
	The drug can only be obtained by the public after speaking with a pharmacist (or other authorized health professional).	The drug can be obtained by the public without intervention, but a pharmacist (or other authorized health professional) must be available/accessible to provide advice prior to purchase.	
	Synchronous consultation with a pharmacist (or other authorized health professional) must occur before the drug can be obtained. • The pharmacist (or other authorized health professional) applies their professional judgment to determine whether the drug is safe and appropriate for the particular individual, based on a fulsome assessment and in accordance with professional standards of practice. • The pharmacist (or other authorized health professional) only provides the drug if they have determined that it is safe and appropriate for the individual.	The drug can be obtained without speaking to a pharmacist (or other authorized health professional), but the individual must be able to obtain synchronous advice from a pharmacist (or other authorized health professional) prior to purchase when desired. • The pharmacist (or other authorized health professional) applies their professional judgment to provide advice about safe and appropriate use of the drug for the particular patient, based on a fulsome assessment and in accordance with professional standards of practice. • The individual would still be able to access the drug even if the pharmacist (or other authorized health professional) advised them against using it.	
	Can be sold at locations that employ a pharmacist (or other authorized health professional). • The location must have policies and procedures in place that prevent the public from accessing the	Can be sold at locations that employ a pharmacist (or other authorized health professional). • The location must have policies and procedures in place to ensure that the public has an opportunity to easily ask for and obtain	

Conditions of Sale	Intervention Required Prior to Purchase	Advice Available and Accessible Prior to Purchase	General Sales
	drug until a consultation with the pharmacist (or other authorized health professional) has occurred and the pharmacist (or other authorized health professional) has determined that that the drug is safe and appropriate for that individual.	synchronous advice from a pharmacist (or other authorized health professional) prior to purchasing the drug.	
	A prescription is not required.	A prescription is not required.	A prescription is not required.
Privacy and confidentiality	The pharmacist (or other authorized health professional) must comply with all professional standards and ethical, legal, and regulatory expectations to protect patient privacy and confidentiality during the intervention, whether in-person or virtual.	If a patient seeks out advice, the pharmacist (or other authorized health professional) must comply with all professional standards and ethical, legal, and regulatory expectations to protect patient privacy and confidentiality during the provision of advice, whether in-person or virtual.	There are no requirements related to speaking with a pharmacist (or other authorized health professional). However, if a discussion occurs, the pharmacist (or other authorized health professional) must comply with all professional standards and ethical, legal, and regulatory expectations to protect patient privacy and confidentiality, whether in-person or virtual.
Documentation	The pharmacist (or other authorized health professional) must document the interaction with the individual in accordance with professional standards and all ethical, legal, and regulatory expectations.	The pharmacist (or other authorized health professional) should document the provision of advice to the individual when deemed necessary, in accordance with professional standards and all ethical, legal, and regulatory expectations.	There are no requirements related to speaking with a pharmacist (or other authorized health professional). However, if a discussion occurs, the pharmacist (or other authorized health professional) should document the discussion when deemed necessary, in accordance with professional standards and all ethical, legal, and regulatory expectations.

Directions on how to provide your feedback can be found in the Consultation Feedback section of this report.

Consultation Feedback

Following internal research, PRA WG and MSAT engagement, and further refinement of the information, NAPRA has developed the above information related to determining the most appropriate drug scheduling model for a modernized program, including conditions of sale. We are now seeking additional input from external organizations, the public, and other interested parties, who have an interest in the future of the National Drug Schedules program.

How to Participate

NAPRA is seeking comments from the following types of organizations and individuals:

- Patient/public organizations interested in public health initiatives;
- The general public who is interested in how NPDs are sold in Canada;
- Federal, provincial, and territorial government officials who work on behalf of the government on files related to NPDs;
- Industry organizations who make/sell NPDs;
- Pharmacists and pharmacy technicians;
- Pharmacy retailers and associations representing them;
- Pharmacy associations representing pharmacy professionals and other arms of the profession;
- The pharmacy regulatory authorities across Canada;
- Provincial and territorial regulators involved in overseeing the regulation of dentistry, dental hygiene, dietetics, medicine, midwifery, naturopathy, nursing, optometry, paramedics, podiatry, and other regulated health professions, as appropriate; and,
- Domestic and international researchers/academics whose work involves the regulation and sale of NPDs in Canada and abroad.

All feedback is to be submitted to NAPRA using the Microsoft Forms linked here. We ask that you only provide comments using this forum, as it will allow NAPRA to organize and synthesize all comments in a timely and efficient manner. Additionally, we ask that only one response per organization be submitted. The consultation will be open for comments until 4 p.m. Eastern Time on July 19, 2024.

Thank you in advance for taking the time to review the information and provide feedback on this phase of the NDS Modernization Project. NAPRA greatly appreciates your collaboration and welcomes any comments you may provide. Should you have any further questions please contact ndsmodernization@napra.ca.

Appendix 1: Background Research Summaries

Value of scheduling/Value of schedules II/III

A 2018 report commissioned by NAPRA and written by Belanger and O'Grady summarized the drug scheduling systems for NPDs in other international jurisdictions and reviewed the data regarding the value of pharmacist-only and pharmacy-only categories. As part of this project, another scan was completed in 2023 to determine if any new work had been generated since the completion of the 2018 report.

In summary, the Belanger and O'Grady report found no information directly comparing harms from NPDs between different drug scheduling systems internationally.[5] In the absence of direct evidence, the authors examined additional information on the potential value of pharmacist-only and pharmacy-only schedules. The report did find studies documenting harms with the use of NPDs and that pharmacists do help by identifying drug therapy problems with NPDs. Their report did not find any studies that linked pharmacist involvement in the sale of Schedule II and III drugs to concrete health outcomes. However, some simulated patient studies suggested that a proportion of pharmacists do provide effective counselling with the potential for improved outcomes and patient safety. Some surveys and observational studies also showed the avoidance of healthcare resources due to pharmacist intervention around NPDs. Overall, the authors concluded that there was not enough evidence to support the superiority of one drug scheduling system over another, but there were some indications of the possible benefit of pharmacist intervention or advice.

There was not a significant amount of new information produced between 2018 and 2023. The literature and international information not previously captured in the Belanger and O'Grady report also provided no evidence that directly compared the safety, health outcomes or other positive attributes of one drug scheduling system versus another. A few articles were found relating indirectly to the benefits and risks of drug scheduling systems, with some indication of potential risks to increasing access and some indication of increased consumer comfort with purchasing NPDs in a pharmacy setting.

Additional information on the drug scheduling systems in other jurisdictions demonstrated that most of those countries have a drug scheduling system for NPDs that includes some restrictions on the sale of NPDs beyond a general sales category. Some countries that do not currently have additional restrictions on the sale of NPDs are recommending that some be put in place, recognizing that additional support may be needed by some patients and that pharmacists have a potential role in preventing and mitigating the risks of NPDs.

Product labels

The literature related to the value of product labelling highlighted that the product label contains important information that consumers need to use NPDs safely and appropriately. Industry has and continues to abide by the rules laid out to tailor labels based on the latest evidence to help with safe and appropriate use of NPDs in Canada. However, the literature did emphasize that even a well-designed label cannot be effective if it is not read by the end user.

[5] Belanger D, O'Grady T. Review of Schedules II and III. Prepared for the National Association of Pharmacy Regulatory Authorities. December 2018.

Overall, the studies found indicate that some but not all individuals read labels. It is worth noting that those who do read the information may only do so upon purchase, may not retain that information or may pick and choose what pieces of information they read. Among those who do read labels, the research demonstrates that they do not necessarily understand the information they have read. Consumer comprehension of label information varies, with certain factors increasing the risk of lack of full understanding of label information. In some studies, a potentially concerning number of individuals were unable to understand label information enough to select and use NPDs safely and appropriately. While efforts have been made to mitigate the risks with the implementation of modernized labels and supporting information so they are easier to understand, there is little to no information available that shows these recent changes have resulted in positive health outcomes at the population use level.

Given deficiencies in the tendency of individuals to read product labels, and the lack of understanding that occurs in those who do read labels, especially for vulnerable populations, it is not surprising that the research also shows that there are segments of the population that would benefit from additional support beyond labelling when it comes to the safe and appropriate selection and use of NPDs. Once again, more vulnerable populations, such as children, the elderly, those with lower health literacy or lower language proficiency, among other parameters, are more likely to require additional support in their selection and use of NPDs. When it comes to this additional support, health professional intervention, particularly by pharmacists, was consistently noted as one of the preferred ways for consumers to obtain that additional support.

In general, NPDs have a strong safety profile and are mostly used by consumers without significant safety issues. However, this does not necessarily mean that they are always used appropriately. The findings demonstrate the limitations of labelling alone in ensuring safe and appropriate selection and use of NPDs. Labels can be difficult to read, difficult to understand, and cannot be tailored to an individual user's specific situation. As such, there still seems to be the need for some sort of support to help at least certain segments of the population with the safe and appropriate selection and use of NPDs. It appears that health professional intervention is the preferred method for consumers to obtain additional support.

Scheduling by ingredient vs. by product

NAPRA reviewed previous discussions on this issue as well as the pros and cons of the two different options for scheduling – either by ingredient or by product. Overall, the past review of the program, as well as additional research conducted, provided only a small amount of information on the topic. Generally, there was minimal direct evidence to suggest one way of scheduling was superior to the other. By using a pros and cons analysis there appeared to be more benefits and fewer disadvantages to scheduling by ingredient versus by product. Further details on this are part of the Preliminary Questions section of this report.

Role of other health professionals

Previous reports and research suggested that the current NDS model is too pharmacy centric. As such, the NAPRA Board of Directors suggested that through the modernization process, part of the project should examine ways to incorporate or leverage other regulated health professionals as part of the program. To gather information from other health professionals, NAPRA used a brief survey that was sent to provincial and territorial regulators involved in overseeing the regulation of dentistry, dental hygiene, dietetics, medicine, midwifery, naturopathy, nursing, optometry, paramedics, and podiatry.

Questions focused on their current understanding and use of the existing NDS program, sought to understand if there were any barriers or positive impacts of the NDS program on their profession currently, if any of the health professions had existing guidance, policies and/or laws related to the NDS and if they had any other suggestions or information for NAPRA to consider as efforts are made to modernize the program.

This survey closed in October 2023, with nineteen organizations providing input. Overall, many of the regulatory bodies were aware of the NDS program and use it to different degrees to support their work. Regarding the question on if changes to the NDS would impact their profession, the response in many cases was “it depends.” This is logical as it is hard to predict how a change could impact something without knowing the details of that change. NAPRA pooled the feedback gathered and generated a list of ideas about how changes to the NDS could have a positive impact in general, which we think could be applicable to many different health professions. As such, through the proposed changes to the scheduling model and conditions of sale, NAPRA is seeking input on how/if other health professions could be impacted by a modernized NDS program that no longer prohibits their involvement in the sale of NPDs, if appropriate provisions are set out within the scopes of practice within their jurisdictions (recognizing that this might require changes to their provincial/territorial law, depending on the jurisdiction). Further details on this are part of the Review of Scheduling Options section of this report.

Appendix 2: Key Considerations

Option A – two categories

In this option, the model would include a schedule of drugs that require intervention prior to purchase and a general sales category. This option would not include a category where advice would be available/accessible (but not required) prior to purchase.

Key considerations – two categories:

- This option is like the model in the U.K., which includes a general sales category and a category of drugs that are not available for self-selection and must be sold under supervision of a pharmacist. As noted in Appendix 1, there are no studies directly comparing or providing evidence that the U.K. system is better or worse than the existing system in Canada, the system in the U.S. or any other system in other jurisdictions.
- If Option A is selected, the classification of products into one of two categories is an exercise that would need to be undertaken at a later phase of the project. It is possible that, when looking at the existing three-tier system, some products in the current Schedule III may need to move to an 'intervention required' category. However, some may move to the 'general sales' category.
- Having an 'intervention required' category would provide strong support to patients for their selection and use of NPDs that are placed in that category, but there would be less support available for other medications versus Option B. As noted earlier, there are certain situations or certain populations, including vulnerable populations, in which additional support beyond labelling is required for safe and appropriate selection and use. Option A would provide additional support for medication in the 'intervention' category only. When compared to Option B, this would provide less support for patients overall, which may be particularly important for more vulnerable populations and could potential lead to inequity for such groups.
- It has been suggested that Option A may result in more access and more autonomy for consumers to manage their own self-care versus Option B. However, through the discussions with the expert groups, this became less certain. Theoretically, having only two categories could result in more NPDs being moved to the 'general sales' category where they would be more accessible since they could be purchased from any location. This could be especially helpful in remote areas. However, anything not categorized as 'general sales' would have to be placed in the 'intervention category'. While pharmacists are generally available and accessible to the public, a consumer may still need to wait until someone can speak with them, making the time required to obtain the product longer. This could reduce access versus Option B for any current Schedule III drugs that are moved to an 'intervention required' category. It is not yet clear whether more drugs would move to 'general sales' or whether more drugs would move to the 'intervention' category, making it hard to assess whether Option A would truly improve access and patient autonomy.
- Both Option A and Option B would allow patients to potentially purchase drugs online, as long as the requirements for advice prior to purchase or intervention prior to purchase were met. This reduces the differences between the two options in terms of access and autonomy.
- The two-category model raised some concerns that such a change would result in less flexibility. Option A would provide fewer options for handling the different levels of risk and different access needs related to the unique characteristics of different NPDs than Option B. The only option available

to deal with any level of risk would be the 'intervention' category, which might not be the appropriate level of oversight in all cases.

- If more NPDs were made available via a general sales category, it is important to note that, in South Korea, as access to OTC drugs increased, the reported cases of adverse drug reactions also increased by an annual rate of 6.86% from 183,554 in 2014 to 259,089 in 2020.[6] It is not clear whether confounding factors were thoroughly assessed in this study, but it still provides an indication of potential risk to increasing access to NPDs.
- Having an 'intervention required' category allows for strong oversight over the drug supply chain to ensure appropriate storage of drugs and to help minimize any risk of inversion or diversion, but only for drugs placed in that category. This oversight of the drug supply chain is of particular importance for certain NPDs that have specific storage conditions, such as those requiring refrigeration, or that are at risk for inversion/diversion. This option would provide a means of ensuring that these drugs are handled by authorized health professionals, who would be trained in handling medications, and who are subject to the oversight of their regulators, as compared to general retail locations. However, there could still be risks of inappropriate storage, inversion, and diversion of any NPDs not placed in the 'intervention' category. As highlighted above, it is likely that some of the drugs currently in Schedule III would become 'general sales' with this option, resulting in an overall increase in the number of drugs with less oversight of storage and handling.

Option B – three categories

In this option, the model is most similar to the status quo that is currently in place in Canada. There would be a general sales category, a schedule for drugs where advice must be available/accessible prior to purchase for those who want it (but is not required), and a schedule for drugs that require intervention prior to purchase.

Key considerations – three categories:

- The existing Canadian model has been in place since 1995 and generally serves all interested parties well. However, NAPRA has documented some issues and thus changes would still be made to the policies and procedures, in subsequent phases of the project if this model were chosen, to make the necessary improvements to address those other issues. Those issues have been documented and categorized into groups related to system issues, process issues, operational issues, and implementation issues.
- Option B would provide strong support to patients for the selection and use of NPDs in both the 'intervention' and 'advice' categories. As noted earlier, there are certain situations or certain populations, including vulnerable populations, in which additional support beyond labelling is required for safe and appropriate selection and use. Option B would provide more options for patient support for a greater number of NPDs, since it is expected that at least some NPDs would move to 'general sales' in Option A. Option B would provide more support for patients overall, which may be particularly important for more vulnerable populations and could possibly contribute to better equity for such groups.
- It has been suggested that Option B may result in less access and less autonomy for consumers versus Option A. However, as noted under Option A, this may not actually be the case. It is not yet clear whether more drugs would move to 'general sales' or whether more drugs would move to the 'intervention' category with Option A. If more drugs move to the 'intervention' category, Option B might actually provide better access and autonomy.

[6] Kim M, Suh D, Barone JA, Jung SY, Wu W, Suh DC. Health literacy level and comprehension of prescription and nonprescription drug information. *Int J Environ Res Public Health*. 2022;19(11):6665. Published 2022 May 30. doi:10.3390/ijerph19116665.

- Both Option A and Option B would allow patients to potentially purchase drugs online, as long as the requirements for advice prior to purchase or intervention prior to purchase were met. This reduces the differences between the two options in terms of access and autonomy.
- It was noted through MSAT and PRA WG discussions that the 'advice" category plays an important role in the NDS program. Having three categories provides flexibility when there is some uncertainty about the NPD, but it does not necessarily require intervention before purchase. The existence of this additional category provides more flexibility to deal with the uniqueness of various types of NPDs, as well as particularities related to the indication, population, dose, and package size of drugs. This option would allow for more specific tailoring of oversight based on the characteristics of the different NPDs.
- Lastly, this option maintains strong oversight over the drug supply chain for a greater number of NPDs, to ensure appropriate storage and to minimize the risk of inversion and diversion since it is expected that at least some NPDs would move to 'general sales' in Option A. As noted, this oversight is of particular importance for certain NPDs that have specific storage conditions, such as those requiring refrigeration, or that are at risk for inversion/diversion. This option would ensure that most NPDs are handled by trained individuals who are subject to the oversight of their regulators.

Removing barriers for other regulated health professionals

Key considerations – removing barriers for other regulated health professionals:

- The proposed high-level approach is not to prohibit other regulated health professionals from leveraging their competence and expertise to support patients with the purchase and use of NPDs within their scope of practice, and to place the responsibility for enabling and enforcing this with the respective health profession regulators. It would not be within the role or authority of NAPRA and its members to play a role in determining or enforcing the rules for other health professions, but neither would it be appropriate for the NDS to limit the role these health professionals can play when providing patient care related to NPDs.
- This approach aligns with the indications from the background research and the direction from the NAPRA Board of Directors that consideration should be given to the role of other health professionals beyond a pharmacist.
- If the NDS program no longer prohibited other authorized health professionals from providing oversight, access to NPDs could increase versus the current system. This could be particularly useful in very remote areas of the country where there are fewer pharmacies and would open the possibility of having some NPDs available in other healthcare establishments. This potential for increased access in a variety of other healthcare settings (e.g., medical clinics), under the supervision of other regulated health professionals (e.g., nurse practitioners), may be particularly important as pharmacy human resource challenges lead to more limited pharmacy hours, especially in some more rural and remote locations. Even with the potential for online sales, as long as the requirements for advice prior to purchase or intervention prior to purchase are met, access could potentially be improved as a greater number of health professionals could potentially provide virtual advice or intervention, making it easier and quicker to access NPDs.
- Some concerns have been expressed about the expertise of other health professionals, indicating that pharmacists are the drug therapy experts and thus those best placed to provide advice on drug therapy. It is true that not all health professions would be competent to assess patient selection and use of all NPDs. However, it is also true that many health professions would definitely be competent, and perhaps even more competent than pharmacists, with regard to certain NPDs (e.g., optometrists and eye medications). For this reason, the authority of other health professionals would be limited to those drugs that the health professional is authorized to provide by their scope of practice (e.g., optometrists

limited to eye-related products), which would be determined based on their competencies by their respective regulatory authorities. This rigour of oversight by the regulator of that health profession should allay any potential safety concerns with this option. It should be noted that other health professionals are already providing advice and consultation to their patients about NPDs within their scope of practice, it is just that at this time, patients often then must visit a pharmacy to purchase the NPD. It may be easier and quicker for patients if they could purchase the NPD directly from that health professional instead of having to visit a pharmacy afterwards. Engagement with the PRA WG and MSAT, as well as direction from the NAPRA Board of Directors, has confirmed that the majority of those engaged see the potential value that other health professionals could provide regarding access to NPDs within their respective scopes of practice.

- Some concerns have also been expressed with the feasibility of this option, as it is unclear whether other health professionals would even be interested in selling NPDs, given many factors, including (but not limited to) the need for space for appropriate storage that does not allow patients to self-select and the administrative time and costs of appropriate inventory management. Therefore, it is possible that even if enabled, this would not be taken advantage of and thus consumers would not get the benefits of increased access.
- There could also be a potential impact on the supply chain with this model. Other health professionals may not have the same infrastructure for inventory management, nor the same level of staff training in inventory management as pharmacies, who are more used to dealing with many different types of medication. However, many health professionals would have such competencies. Further, these locations would be under the oversight of a health profession regulator, versus a general retail outlet with much less oversight. The supply chain may also experience strain on delivery resources as the number of locations placing orders could increase and smaller deliveries to more locations would be required.
- To date, other health professions have not shown a strong interest in participating in the NDS program. Fully including them in operations would require them to participate in the development and implementation of the program, which they may not wish to do given other priorities. Therefore, NAPRA is proposing an approach that does not prohibit other regulated health professionals from leveraging their competence and expertise to support their patients with the purchase and use of NPDs within their scope of practice, and places the responsibility for enabling and enforcing this with the respective health profession regulators. Should a profession not be interested, or the regulator determine that it is not appropriate, involvement would not need to be enabled for that profession.
- There were also questions about who would be responsible for enforcement. As pharmacy regulators, NAPRA and its members would not have authority over other health professionals and as such, the role of enforcement would have to be conducted by the other health professional's regulator. This approach provides other health regulators with the option of whether or not to enable this ability for their profession. If they do not feel able to provide enforcement and oversight, or do not feel it appropriate, they would simply not take action to enable it.
- There were also some concerns about ensuring harmonization of expectations between the different authorized health professionals providing NPDs. The definition of authorized health professional included in the consultation materials clearly states that all the conditions of sale of the NDS would need to be followed, regardless of the health profession. NAPRA would also be available to provide support to any health profession looking to implement this option to further enhance alignment.
- This approach would also improve the adaptability and flexibility of the modernized NDS program, in that as the scope of practice of other health professions changed over time, they could be enabled by that health profession regulator, without requiring any significant changes to the NDS program.

Appendix 3: Survey Questionnaire

Thank you for taking the time to provide input on this phase of the NDS Modernization Project. The questions presented in this questionnaire should be viewed in conjunction with the consultation document report, available on the NAPRA website. The purpose of the consultation is to gather information from many interested parties who are impacted by the NDS program. The goal will be to address the following topics:

1. Addressing two preliminary questions for the NDS program structure:
    - Should the modernized model schedule by ingredient or by product?
    - Should the modernized model have a prescription-only category?
2. Confirming which scheduling model is most appropriate for a modernized NDS program, and
3. Determining the conditions of sale to accompany the modernized NDS program.

We are now seeking additional input on these components of the project. NAPRA sincerely appreciates your feedback and collaboration. Should you have any further questions, please contact ndsmodernization@napra.ca.

To submit feedback, we ask that you use this link to a Microsoft Forms document. We ask that you only provide comments using this forum, which will allow NAPRA to organize and synthesize your comments in a timely and efficient manner. If you are participating in this consultation on behalf of an organization, we ask that only one response per organization be submitted.

Preliminary Recommendations

Information about the recommendations is outlined on pages 5-8 of the consultation document.

Question 1.

Do you support the following recommendation?

Recommendation 1: that the NDS continue to schedule by ingredient, with provisions to allow exceptions to be made based on specific circumstances (e.g., specific elements beyond the ingredient itself that affect safety and efficacy).

Yes, I support this recommendation
No, I do not support this recommendation

If not, please provide your reason(s) for not supporting the recommendation.

Long form answer box

Question 2.

Do you have any additional comments to share with NAPRA related to this recommendation?

Long form answer box

Question 3.

Do you support the following recommendation?

Recommendation 2: that NAPRA not maintain a separate prescription category, as long as a pharmacist (or other authorized health professional) intervention category is maintained.

Yes, I support this recommendation
No, I do not support this recommendation

If not, please provide your reason(s) for not supporting the recommendation.

Long form answer box

Question 4.

Do you have any additional comments to share with NAPRA related to this recommendation?

Long form answer box

Scheduling Options

Information about the proposed scheduling options are outlined on pages 8-11 of the consultation document. Additional details regarding the key considerations of the two options are outlined in Appendix 2 of the consultation document, on pages 18-21.

Question 5.

When considering Options A and B, which option would you select for a modernized NDS program?

Options	*Intervention Required Prior to Purchase	*Advice Available and Accessible Prior to Purchase	General Sales
Option A	X		X
Option B	X	X	X

**The intervention or advice noted in each category must be provided by a pharmacist. It may be provided by another authorized health professional only if that ability has been enabled and will be enforced by the regulator of that profession. In all cases, the conditions of sale would need to be followed. Please see the definitions of authorized health professional, available and accessible as well as the proposed conditions of sale for more details.*

Option A
Option B
No opinion/I don't know
Neither

Question 6.

Please provide your rationale for this selection.

Long form answer box

Question 7.

When thinking of the two options presented, please indicate your level of comfort with Option A.

This is the option I would prefer for the drug schedule model
This option is not my preferred option, but would be acceptable for the drug schedule model
This option is not acceptable for the drug schedule model
No opinion/I don't know

Question 8.

Using the options presented below, please indicate your level of comfort with Option B.

This is the option I would prefer for the drug schedule model
This option is not my preferred option, but would be acceptable for the drug schedule model
This option is not acceptable for the drug schedule model
No opinion/I don't know

Question 9.

Do you have any feedback on the following definition?

Available: means the pharmacist (or other authorized health professional) is physically present in an in-person sales environment and is able to talk to the patient about the drug before it is purchased. If the sale environment is virtual, the pharmacist (or other authorized health professional) can be synchronously reached in real time and is able to talk with the patient about the drug before it is ordered.

Long form answer box

Question 10.

Do you have any feedback on the following definition?

Accessible: means the patient is capable of easily speaking with the pharmacist (or other authorized health professional). If in person, the pharmacist (or authorized health professional) is easy to approach and there are no barriers present that reduce the chance of reaching the pharmacist (or other authorized health professional) to converse about the drug prior to purchase. If the environment is virtual, it is easy to follow the prompts to synchronously reach a pharmacist (or other authorized health professional) to converse about the drug prior to purchase.

Long for answer box

Question 11.

Do you have any additional comments to share with NAPRA related to the selection of a model for a modernized NDS program?

Long form answer box

Conditions of Sale

Information about the proposed conditions of sale are outlined on pages 11-13 of the consultation document.

Question 12.

What feedback do you have on the content under “Access to the drug”?

Long form answer box

Question 13.

What feedback do you have on the content under “Privacy and confidentiality”?

Long form answer box

Question 14.

What feedback do you have on the content under “Documentation”?

Long form answer box

Question 15.

Do you have any additional comments to share with NAPRA related to the proposed conditions of sale for a modernized NDS program?

Long form answer box

Removing barriers for other regulated health professionals

Information about removing barriers for other regulated health professionals is outlined on pages 20-21 of the consultation document.

Question 16.

NAPRA is proposing that the modernized NDS structure be designed to not prohibit other regulated health professionals from leveraging their competence and expertise to support their patients with the purchase and use of NPDs within their scope of practice but to place the responsibility for enabling and enforcing this with the respective health profession regulators. This is being proposed because it would not be within the role or authority of NAPRA and its members to play a role in determining or enforcing the rules for other health professions, but neither would it be appropriate for the NDS to limit the role these health professionals can play when providing patient care.

The NDS model would broadly categorize non-prescription drugs as either requiring intervention from a pharmacist or other authorized health professional prior to sale or in a category where advice is available and accessible from a pharmacist or other authorized health professional, but not required,

prior to purchase (if a three-category model is chosen). It would be up to the regulatory authorities for each of the professions in each of the Canadian jurisdictions to examine their regulatory requirements, determine whether they will make any modifications to allow their registrants the authority to engage in the sale of non-prescription drugs listed in the NDS, and to enforce compliance with the general conditions of sale of the NDS, and any additional standards and rules around the sale of non-prescription drugs for their profession.

Do you agree with this approach?

Yes
No
No opinion/I don't know

Question 17.

Please provide your rationale for this selection.

Long form answer box

Question 18.

Do you have any feedback on the following definition?

Authorized Health Professional: For the purposes of the National Drug Schedules program, an authorized health professional is a regulated health professional whose legal scope of practice allows them to assess individuals and recommend non-prescription drugs that are listed in the National Drug Schedules. The authorized health professional may only sell non-prescription drugs listed in the National Drug Schedules:

i. if they have been authorized to recommend and sell that drug according to the legal scope of practice and other regulatory requirements of their profession, as determined and enforced by the regulatory authority of that profession, and,

ii. in accordance with the conditions of sale of the NDS, to be enforced by the regulatory authority of that profession.

Long for answer box

Concluding comments

Question 19.

Considering all aspects of this phase of the NDS Modernization Project, do you have any additional comments to share with NAPRA?

Long form answer box

Demographics

Question 20.

Please provide the following information:

Name:
Organization:
Email address:

Question 21.

Please select the demographic category that best matches why you are participating in this consultation.

Drop down menu:

- *Patient/public organizations interested in public health initiatives*
- *General public*
- *Federal government official*
- *Provincial/Territorial (P/T) government official*
- *Industry association on behalf of membership*
- *Individual industry organization who makes/sells non-prescription drugs*
- *Pharmacist*
- *Pharmacy technician*
- *Pharmacy retailer*
- *Pharmacy Regulatory Authority*
- *Association representing pharmacists/pharmacy technicians/pharmacy practice/pharmacy retail*
- *P/T regulator of dentistry*
- *P/T regulator of dental hygiene*
- *P/T regulator of dietetics*
- *P/T regulator of medicine*
- *P/T regulator of midwifery*
- *P/T regulator of naturopathy*
- *P/T regulator of nursing*
- *P/T regulator of optometry*
- *P/T regulator of paramedics*
- *P/T regulator of podiatry*
- *National organization representing a regulated health profession*
  - *Indicate which profession*
- *Researchers/academics*
  - *Indicate area of specialty*
- *Other*
  - *Indicate other affiliation*