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

The Canadian Pharmacists Association (CPhA) would like to thank NAPRA for the opportunity to participate in this consultation determine the most appropriate drug scheduling model for the future, including conditions of sale. Our responses to this consultation are informed by our vast experience in this area, as well as our engagement with front line pharmacists and the patients that they serve.

Preliminary Recommendations

Question 1: Do you support the following recommendation?

NAPRA Recommendation 1: **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

Question 2. Do you have any additional comments to share with NAPRA related to this recommendation

Scheduling drugs by ingredient provides more consistent regulation and streamlined enforcement. This approach simplifies the training of healthcare providers, pharmacists, and law enforcement, as they need only understand the regulations for specific ingredients, rather than a great number of individual products. Additionally, listing by ingredient facilitates the monitoring and tracking of drug use, thereby aiding in the identification of trends in abuse or misuse more effectively. Scheduling by ingredient also mirrors the way that healthcare providers, such as pharmacists, evaluate the appropriateness of a medication choice (i.e., interactions, safety, efficacy, etc.) and how medication research is conducted, as well as makes it easier for new products to enter the market because it is not required to schedule every single product.

<u>Considerations:</u>

- The process of reviewing and granting exceptions could be resource-intensive and slow, potentially delaying access to beneficial medications and a process should be in place to minimize this.

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Question 3: Do you support the following recommendation?

NAPRA Recommendation 2: **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

Question 4. Do you have any additional comments to share with NAPRA related to this recommendation

Recognizing that evaluation for the necessity of prescription medication status is being done by Health Canada, we agree with removal of NAPRA's prescription category.

Considerations:

- How may scheduling by reference be impacted. A process will need to be in place to manage this in collaboration with provincial regulatory authorities so they may adjust as required.
- It will be necessary to clearly define NAPRA's revised role, especially pertaining to what NAPRA will and will not govern regarding prescription drugs. The process for drugs that are removed from the Prescription Drug List and given non-prescription drug status will need to be defined.
- It would also be helpful to clarify the process for non-prescription drugs (according to Health Canada) which remain on NAPRA's Schedule 1 as no request for scheduling was submitted - for example, whether they will automatically be moved to the 'intervention required' category.

Scheduling Options

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

Considering patient safety and respecting pharmacist capacity within the current system, Option B, which maintains a Schedule 3 equivalent, is the best choice.

We have the following concerns with option A:

Patient safety:

- Patients purchasing general sale items, especially those previously in Schedule 3, may not have the opportunity to consult a pharmacist or other healthcare professional leading to incorrect use and harms.
  - This is especially important for many patient populations, including but not limited to:
    - Patients with multiple comorbidities or who take multiple medications
    - Patients whose primary language is not English or French
    - Patients who are managing a new condition
    - Patients managing medications for pediatrics and children
    - Older adult patients or their caregivers
    - Patients belonging to Canada's most vulnerable populations
- Patients purchasing general sale items which were previously Schedule 3 may receive advice from non-healthcare professionals when purchasing. This can have dangerous consequences such as inaccurate advice leading to harms, overuse of medications that can cause harm (e.g., acetaminophen), or lengthened duration of illness due to ineffective treatment.
  - Example: We have already seen these complications with Canada's medical cannabis users, who typically do not have access to healthcare professionals at the time of purchase (Recommendation 43, Rosenberg et al. 2024)[1] The harms created by this situation are among the reasons that the Expert Panel for Legislative Review of the *Cannabis Act* has recommended that medical cannabis be dispensed in pharmacies. Learning from the conditions of sale in the *Cannabis Act,* Option A runs the risk of having to rework the drug scheduling model again in the future due to unintended harms caused by it.

- Pharmacist capacity and remuneration
  - Potential redistribution of some Schedule 3 items to the intervention required category increases the need for pharmacist availability for patient engagement, assessments and documentation. Given that there are no provisions in place around staffing requirements for pharmacy operations, this may not be feasible for locations with only one pharmacist on duty at a time.

    - Consider: If more pharmacist presence is required to support increased patient engagement during NPD selection, a plan should be in place to support the sustainability of new practice workflows with thought given to factors such burnout within the pharmacy workforce, depleted health human resources, and the current funding models in place which are unfortunately unable to support the evolution of pharmacy services.
    - Consider: additional space behind the counter and in the dispensary are also required to accommodate changes proposed in Option A. This may worsen the unlevel playing field for smaller independent pharmacies who may not be able to adjust their dispensary size to accommodate the change.
- Compromised medication accessibility
    - Increases to pharmacist workload without consideration of dispensary and pharmacist capacity will result in increased wait times for patients, as they will be required to consult with the pharmacist for medications which they may have previously been able to access. The alternative is that they have increased access to medications, but reduced access to the advice of a trained medical professional, and thus at higher risk of adverse drug events.

[1]Rosenberg M, Ayonrinde O, Conrod, PJ, Levesque LL, Selby P. Legislative review of the Cannabis Act: final report of the expert panel. Published March 2024. Accessed July 17, 2024. https://www.canada.ca/en/health-canada/services/publications/drugs-medication/legislative-review-cannabis-act-final-report-expert-panel.html#a11.

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

Increasing clarity

- To increase clarity, consider adding "…is able to intervene in a sale if necessary, and when requested, to answer questions, offer advice, and ensure that patients understand their medications before use".
- Example of intervening in a sale if necessary: The pharmacy team notices adolescents self-selecting non-prescription drugs.
- To further increase clarity, consider restructuring the sentence to identify the in-person sales environment before the pharmacist requirements, i.e., "Available means that, in an in-person sales environment, the pharmacist… is physically present and able to talk to the patient…" This reflects the sentence structure used in the following sentence.

Considerations

- As the world of pharmacy continues to evolve, pharmacies may pursue mixed in-person and virtual services. To ensure future-proofing of the NDS, it is important to consider altering the definition of "available" so that it does not restrict pharmacies from offering synchronous virtual advice during the in-person visits of patients.
- Given the ever-increasing incorporation of artificial intelligence into workflows, it is important to consider adding wording that reflects that any virtual or synchronous advice must come from authorized or accredited software.

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.

- Consider replacing the "capable" with …means patient "can easily communicate with the pharmacist…".
    - 'Capable' could be interpreted as the patients' personal capacity (disability, language), and not the pharmacy's ability to provide the service.
- Consider removing the stipulation that there be no barriers to approaching the pharmacist as removal of all barriers will result in increased pharmacist interruptions, which lead to stress, burnout, and medication errors and may compromise patient safety. Instead, consider requiring that there be sufficient systems in place for pharmacy staff to signal to

the pharmacist that a patient requires pharmacist consultation, with the goal of minimizing pharmacist distractions.
    - Additionally, there should be an expectation built into this definition that patients may need to wait to speak to a pharmacist.
- Consider expanding this definition to permit virtual pharmacist assistance during patients' in-person pharmacy visits to accommodate pharmacies that have pursued or wish to pursue mixed virtual and in-person services.

Question 11. Do you have any additional comments to share with NAPRA related to the selection of a model for a modernized NDS program?

Conditions of Sale

Question 12. What feedback do you have on the content under "Access to the drug"?

For category 1 (intervention required): Pharmacists and other healthcare professionals may experience increased workloads, which could impact their ability to provide timely consultations. Staff will need training to ensure they comply with the new requirements and can effectively manage the consultation process. Guidance on this training should be considered.

Some other factors to be considered are:

- Pharmacy Operations:
    - The workflow of non-pharmacy settings to accommodate self-selection with the option of receiving advice from select healthcare professionals, considering the potential challenges in an appointment-based model used by many professions.
    - The physical set up of locations outside the pharmacy setting
    - Hours of operation for many establishments may be decreased compared to pharmacies.
- Drug distribution:
    - Regulation of the sale of products sold at locations other than pharmacies, including access to suppliers and distributors, to ensure continuity of care and prevent increased mark-ups compared to pharmacies.
    - In non-pharmacy healthcare settings: reduced visibility to patients' complete drug profile for assessing medication safety and appropriateness.
    - In non-healthcare settings: no visibility to patients' drug profiles.

Question 13. What feedback do you have on the content under "Privacy and confidentiality"?

Regarding the category 2 (advice available) statement, consider duplicating the wording used in category 1 (intervention required) since privacy and confidentiality extends beyond verbal exchanges with a patient.

Question 14. What feedback do you have on the content under "Documentation"?

For category 1 (intervention required), documenting every non-prescription medication consultation will increase the workload of the pharmacist. For example, if a patient is not a regular patient at a pharmacy, documenting these assessments requires the pharmacist to create a new patient profile, and in certain provinces, access their drug record to check for interactions, etc. This further decreases the efficiency of these encounters and thus inconveniences the patient. It should be left up to the pharmacist's professional judgement whether documentation is required or not.

Question 15. Do you have any additional comments to share with NAPRA related to the proposed conditions of sale for a modernized NDS program?

Medication safety and appropriateness of use should not be compromised for the sake of quick and easy access. Evidence indicates that increased access to NPDs may lead to increased risk of adverse drug reactions, disproportionately affecting vulnerable populations. Adverse drug reactions are preventable with proper assessment and counselling on the correct and appropriate use of a medication. Adverse drug reactions increase the burden on the healthcare system by requiring the use of reactive tertiary care services to mitigate the impacts of the ADR. Developing a system that could compromise the health of patients and worsen Canada's healthcare system is not in keeping with NAPRA's mandate to protect and serve the public interest.

Removing barriers for other regulated health professionals

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 nonprescription 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

While we recognize the potential benefit of not prohibiting other regulated health professionals from assisting patients in the purchase and use of NPDs, such as increased access to non-prescription drugs potentially improving convenience in underserved areas, we note the following as risks and considerations:

- Impacts to patient safety:
    - Different regulatory authorities may have varying standards and enforcement practices. Without a standardized approach, there is a risk that some professionals provide different levels of assessment and advice compared to pharmacists, healthcare's medication management experts, leading to potential misuse or inappropriate use of non-prescription medications in the intervention required and advice available categories.
    - The "independent double check" of the clinician's assessment allowed by the current system (i.e., subsequent pharmacy visit and pharmacist consultation) helps to reduce harm. Evidence indicates that most preventable adverse drug reactions occur due to errors in medication ordering (Leape et al. 1995; Bates et al. 1995).[1,2] These errors are caught by pharmacists, demonstrating the immense value of having a pharmacist evaluate drug recommendations of other prescribers. Caution is needed when considering changes that will reduce opportunities for dual validation of a healthcare provider's assessment.
    - Pharmacies have access to a patient's full medication list, which helps to ensure patient-centered evaluation and recommendations are provided. In other settings, practitioners may not have access to a complete medication list, which could result in drug-drug or drug-disease interactions, duplications of therapy, and other harms to the patient. In the absence of a system to mitigate these concerns, we are likely unable to avoid these harms.
- Confusion regarding access and scope of practice:
    - The lack of a unified standard could create confusion for patients and professionals, complicating the process of obtaining and using non-prescription drugs. For instance, patients may find it difficult to select the appropriate healthcare professional to see for assistance in purchasing required NPDs. Similarly, HCPs may not know which other professionals to refer patients to if they are not qualified to make a recommendation for a given condition or do not have access to the product they'd like to recommend.
    - There could be disputes regarding overlaps in the scope of practice among different health professions, leading to challenges in delineating responsibilities and working together as members of a patient's circle of care.
- Further fragmentation of the healthcare system:
    - There is often little consistency between provinces for regulating healthcare professional scope of practice. The risk of this occurring during the modernization of the NDS must be considered.
- Operations, drug distribution, drug shortages, and recalls:
    - The physical set up and workflow of non-pharmacy settings to accommodate self-selection with the option of receiving advice from select healthcare professionals

may prove challenging and unsafe considering the appointment-based model used by many professions.
    - Having additional sites and practitioners purchasing drug products could have consequences such as additional/prolonged drug shortages, which would then become even more challenging to manage. The distribution of influenza vaccines in Ontario serves as an example of this. Flu shots are available at multiple locations by multiple providers, and, at any given moment, the total supply of influenza vaccine is unclear. Thus, influenza vaccine shortages are that much more complicated to work through than other drug shortages.
    - A system for managing product recalls would need to be in place.
    - The ability of non-pharmacy settings to properly store non-prescription drugs must be considered. At this time, many may not be equipped to accommodate consistent ambient temperature or cold storage requirements, among others, and outfitting multiple new locations with the ability to manage drug storage may create significant financial burden on these practices. This could lead to broader impacts on the healthcare system due to reduced capacity of certain professionals to take on new patients.
- Other:
    - Regulation by other additional organizations for example, in enforcing documentation requirements, storage requirements etc., must be considered to ensure a level playing filed and appropriate purchase, storage and sale..

Given that there are more risks than benefits, we do not agree with the approach summarized in question 16.

[1]Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995;274(1):35-43.

[2]Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA. 1995;274(1):29-34.

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.

No comments

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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?

- Improving the presentation of the NDS on the NAPRA website, along with enhancing the search capabilities of the database, should be added to this project, especially if continuing to schedule by ingredient.
    - Consider linking product names to their ingredients, allowing users to search product names as keywords while maintaining categorization by ingredient.
    - Including multiple search terms for a single entry would enable users to more easily search all scheduled drugs from one entry. For example, searching for "estrogen" or "estradiol" on the NDS yields no results, despite these being listed as prescription by Health Canada, and existing in the NDS under “hormone”. The current set-up could lead to confusion among healthcare professionals who are not familiar with drug scheduling systems in Canada but are required to utilize NAPRA’s NDS.
    - Can NAPRA connect with the Drug Product Database query
    - Can the exemptions/differences between provinces be consolidated and maintained on one webpage.
- Existing pharmacy and associated central systems would need to be overhauled to capture the new requirements, considering associated cost and time requirements.

While we understand that this project is in phase 1B, we believe that it is best to consider how each option would play out in subsequent phases. For example, certain considerations for the model could be eliminated during this phase based on difficulties that may arise during policy development and implementation. A focus on the impact of each phases’ decisions on the next will help simplify future consultations required for the NDS modernization project.

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