

# CHP CANADA’S PROPOSAL FOR INTEGRATION OF DRUG SCHEDULING DECISIONS INTO THE FEDERAL PRODUCT REVIEW PROCESS

Developed upon request for the Treasury Board Secretariat February 2018

Process Element	Option 1: Integration under the Federal Food and Drugs Act	Option 2: Integration of decision-making, while giving effect through Provincial legislation
<p><b>Transition Step 1:</b> Policy development</p>	<p>Health Canada in consultation with an Advisory Committee would publically consult on developing and revising policies with respect to:</p> <ul style="list-style-type: none"> <li>• Description of the drug schedules (Schedule I: Condition of sale requires a prescription pursuant to be sold, Schedule II: Condition of sale requires Pharmacist mediation prior to purchase, Schedule III: Condition of sale requires Pharmacist availability at the point of sale)</li> <li>• Scope of the drug schedules,</li> <li>• Scheduling factors,</li> <li>• Cascading approach to applying the factors, and;</li> </ul>	<ul style="list-style-type: none"> <li>• Consult on maintenance of the National Drug Schedules in policy and as incorporated by reference in Provincial legislation.</li> </ul>
<p><b>Transition Step 2:</b> Legislative and Regulatory Amendments</p>	<ul style="list-style-type: none"> <li>• Federal Regulatory Amendment required to create administrative lists</li> <li>• Provincial legislative/or regulatory amendments to eliminate drug schedules or references to the NAPRA managed National Drug Schedules. They could also leave in place backdrop authority to make exceptions to the National Drug Schedules.</li> </ul> <p>Note: Existing powers under the <i>Food and Drugs Act</i> are sufficient to grant the Department the ability to determine conditions of sale pursuant to Pharmacist interaction, or pharmacist availability) and establish administrative lists administered under a regulation under the <i>Food and Drugs Act</i> (ie. similar to the Prescription Drug List)</p>	<ul style="list-style-type: none"> <li>• Provincial legislative/or regulatory amendments required to reference a Federally managed National Drug Schedules (ie. Remove references to NAPRA)</li> </ul>
<p><b>Transition Step 3:</b> Advisory Committee</p>	<p>Each Province and territory may nominate a member to the Advisory Committee. Appointees can come from government, Provincial Colleges of Pharmacy, academic institutions, health care, consumer, industry groups and the public. Committee participants would have 3 year terms, and serve no more than 3 consecutive terms. Members must have expertise in one or more of the following areas:</p> <ul style="list-style-type: none"> <li>• Regulation of scheduled medicines</li> <li>• Toxicology/pharmacology</li> </ul>	



	<ul style="list-style-type: none"> <li>• Clinical pharmacology</li> <li>• Community Pharmacy practice</li> <li>• Family Medical practice</li> <li>• Consumer health issues</li> <li>• Communication experts</li> <li>• Consumer Behaviour experts</li> </ul> <p>The Committee would also include consumer and industry observers.</p>	
<p><b>Operational Step 1:</b> Health Canada review and approval of the product</p>	<p>After a review of the sponsor’s submission, Health Canada determines that the proposed product does not meet the factors and principles set out in Section C.01.040.3 of the <i>Food and Drug Regulations</i> that require a product to be sold pursuant to a prescription. The sponsor is notified about the outcome of the review, but the Notice of Compliance, and DIN/ or NPN is put on hold until the decision is finalized.</p>	
<p><b>Operational Step 2:</b> Sponsor submission to Advisory Committee to support a scheduling decision</p>	<p>Sponsors would prepare a submission to the Advisory Committee seeking a scheduling decision applying the factors. The Advisory Committee reviews the submission and issues an interim decision for consultation.</p>	
<p><b>Operational Step 3:</b> Public Consultation</p>	<p>Health Canada would consult on revisions to the Prescription Drug List and changes to the Federal Administrative Schedules in accordance with the current process:</p> <ul style="list-style-type: none"> <li>• CGI Notice of Intent is published with 75-day public consultation period on the proposal to amend the Prescription Drug List and the relevant Federal Schedules.</li> <li>• The Advisory Committee and Health Canada review the comments received and prepare the final notice.</li> <li>• Notice of Intent to Amend is published announcing outcome of the public consultation and the changes to the Prescription Drug List and Federal Schedules.</li> </ul>	<p>Health Canada would consult on revisions to the Prescription Drug List in accordance with the current process:</p> <ul style="list-style-type: none"> <li>• CGI Notice of Intent is published with 75-day public consultation period on the proposal to amend the Prescription Drug List</li> <li>• The Advisory Committee and Health Canada review the comments received and prepare the final notice.</li> <li>• Notice of Intent to Amend is published announcing outcome of the public consultation and the changes to the Prescription Drug List. This signals the date on which the National Drug Schedules would be amended (and, by reference, adopted at the provincial level)</li> </ul>
<p><b>Operational Step 4:</b> Implementation</p>	<ul style="list-style-type: none"> <li>• The Notice of Amendment is published 6 months after the Notice of Intent to amend, implementing the changes to the Prescription Drug List and relevant Federal Schedules.</li> </ul>	<ul style="list-style-type: none"> <li>• The Notice of Amendment is published 6 months after the Notice of Intent to amend, implementing the changes to the Prescription Drug List, the National Drug Schedules, and the Provincial Pharmacy Acts.</li> <li>• The Provinces and territories reserve the right to impose a different scheduling decision to address local needs.</li> </ul>

## Frequently Asked Questions

### Q1: Is a legislation or regulatory amendment needed at the Federal or Provincial/Territorial Level?

A1: Option 1: Existing authorities under section 30(1)(b)(iii) of the *Food and Drugs Act* allow for Health Canada to determine conditions of sale for any health product. Under that authority. Health Canada would have to amend the Food and Drug Regulations, to establish the schedules of non-prescription drugs, and the criteria for listing products/ingredients within these administrative lists (ie. Scheduling factors), similar to the process applied when the Prescription Drug List was established. For self-care products that are regulated as Natural Health Products, a consequential amendment to Schedule 2 of the Natural Health Product Regulations would be required to exclude scheduled drugs from the definition of a Natural Health Product. This means that the federal drug schedules would include products that are currently regulated today as non-prescription drugs and natural health products. This structure would mean that any self-care product would be captured by the drug scheduling process if they meet the criteria/factors.

Provincial and Territorial legislative/regulatory amendments would be required to eliminate the scheduling by reference to the National Drug Schedules, and instead refer to the Federal schedules.

Option 2: Yes, consequential amendments would be required for the provinces and territories (Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island) that reference “NAPRA” within their legislation and/or regulation. Quebec would require a regulatory amendment to refer to the National Drug Schedules. Newfoundland and Labrador and British Columbia could continue to administratively adopt the National Drug Schedules, though ideally, these provinces would move to scheduling by reference to the National Drug Schedules.

### Q2: Will the provinces or territories be able to overrule and intervene to establish more restrictive scheduling decisions to address regional concerns?

A2: Option 1: Yes, Provinces or Territories could choose to maintain their own schedules/exceptions, or schedule by reference to the Federal drug schedules.

Option 2: Yes, as existing Provincial and Territorial legislation and regulation will be maintained.

### Q3: How long would it take to accomplish?

A3: Option 1: The necessary Federal regulatory amendments typically take 12-18 months through the Governor in Council process. The necessary amendments to the provincial drug schedules could require regulatory and or legislative measures that would need to be done in parallel with the federal process. A policy consultation will be required on (1) appropriate conditions of sale are (2) the scheduling factors and (3) to review the National Drug Schedules to determine whether they could be adopted federally, or require modification (especially if the Quebec Schedules are to be harmonized and integrated federally). These policy consultations would be required as a prerequisite to the regulatory consultation, which may take up to 12 months.

Option 2: Should Health Canada choose to administratively take over the existing National Drug Schedules structure and process, this could be done, even as an interim measure prior to the creation of the Federal regulatory model. This could be accomplished in as little as 12-18 months. Consequential amendments to provincial regulations which currently reference NAPRA would have to be carried out.

**Q4: How would costs be recovered?**

A4: Under Health Canada's current cost recovery regime, cost recovery would only be possible through federal regulation.

**Q5: How would a transition to a new system be managed?**

A5: It may be appropriate, even if Option 1 is agreed upon as the ideal approach, to transition first to Option 2 as a way of bridging from the status quo in a confidence building exercise that would accommodate varying provincial readiness to transition to a Federal regime.

**Q6: How would enforcement work?**

A6: Option 1: Enforcement of the National Drug Schedules would fall to the Regulatory Operations and Regions Branch of Health Canada, as part of their existing mandate for health products regulated under the *Food and Drugs Act*.

Option 2: Enforcement of the National Drug Schedules would continue to fall to provincial pharmacy inspectors as per the status quo.