KEEPING CURRENT WITH DRUG SCHEDULE CHANGES

The College often receives inquiries from members seeking advice with respect to the conditions for sale of specific drug products (e.g., Schedule I, II, III or Unscheduled). This article will help clarify the roles of both Health Canada and NAPRA in drug scheduling.

FEDERAL ROLE

Health Canada determines whether or not a drug requires a prescription. Once Health Canada classifies a drug as requiring a prescription for sale, then it requires a prescription for sale in all of Canada. The drug is placed on the Prescription Drug List[1] maintained by Health Canada. This list has replaced Schedule F to the *Food and Drug Regulations* and was created to make the process simpler and more efficient.

The Prescription Drug List is a list of medicinal ingredients that when found in a drug, require a prescription. However, it does not include medicinal ingredients that when found in a drug, require a prescription if those ingredients are listed in *Controlled Drugs and Substances Act* (CDSA) Schedules. (Ingredients listed in the CDSA Schedules include narcotics, controlled drugs, restricted drugs, benzodiazepines, targeted substances, precursors, industrial hemp and marihuana for medical purposes.) Prior to the adoption of the Prescription Drug List, a regulatory amendment was needed to give a drug prescription status by adding it to Schedule F, or to switch its status from prescription to nonprescription by removing it from Schedule F.[2]

Although regulatory amendments are no longer required, Health Canada does employ a defined process whereby medical ingredients are removed or added to the Prescription Drug List. The process as described by Health Canada includes[3]:

- Health Canada evaluates data from a drug submission/product license application to assess the safety, quality and efficacy of a medicinal ingredient and whether it should be available by prescription only.
- Health Canada scientific staff make a recommendation to the existing Health Canada committee of scientific

PRESCRIPTION DRUG LIST – examples of recent changes:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/notice-avis-eng.php

DRUG	DATE OF NOTICE	EFFECTIVE DATE
Levonorgestrel	2015-05-29	2015-05-29
Naproxen	2015-03-26	2015-03-26
Mometasone furoate monohydrate (Nasonex)	2015-02-12	2015-08-12
Traimcinolone acetonide (Nasacort)	2015-01-14	2015-01-14
Hydrocortisone	2014-12-24	2014-12-25
Lovastatin	2014-12-05	2014-12-05

experts to add or remove a medicinal ingredient from the Prescription Drug List.

- Following endorsement by the Committee, the following steps occur (in this order):
  - o Notice of Consultation posted to the Health Canada website regarding the Department's intent to add or remove a medicinal ingredient from the Prescription Drug List and the rationale for the proposed addition or removal
  - o 75 day consultation
  - o Health Canada evaluates the comments received during the consultation
  - o Notice of Intent to Amend the Prescription Drug List posted to Health Canada website
  - o Notice of Amendment to the Prescription Drug List posted to Health Canada website six months from the date of the posting of the Notice of Intent to Amend. This informs the public that the ingredient has been added and provides the rationale regarding the addition.
- Note: If the drug is new to the Canadian market, a Notice of Amendment is posted to the Health Canada website, informing the public of the ingredient that has been added to the Prescription Drug List and the Department's rationale regarding the addition. There is no consultation period.

Additional information on this process is available on the Health Canada website - http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php.

Notices of changes to the Prescription Drug List, including amendments and consultations are posted on the Health Canada Website - http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/notice-avis-eng.php. Additionally, individuals can subscribe to the Health Canada Prescription Drug List Really Simple Syndication (RSS) feed - http://www.hc-sc.gc.ca/dhp-mps/prodpharma/feeds-fils/index-eng.php.

PROVINCIAL AND NAPRA ROLES

If a drug has been given non-prescription status by Health Canada, it is up to the provinces and territories to determine the appropriate conditions of sale for that drug. Ontario has adopted the National Association of Pharmacy Regulatory Authorities (NAPRA) National Drug Schedules (NDS)[4] and thus amendments made to the National Drug Schedules are effective immediately. The NAPRA Supplemental Standards of Practice[5] guide pharmacists in the level of professional intervention and advice necessary for the safe and effective use of drugs by consumers, according to each Schedule.[6]

When Health Canada approves a switch from prescription to non-prescription status (i.e., removal from Prescription Drug List), the National Drug Scheduling Advisory Committee (NDSAC) formed by NAPRA, will evaluate the change and update the National Drug Schedules. This evaluation only occurs if a submission by a manufacturer to have the drug reviewed by the *National Drug Scheduling Advisory Committee* (NDSAC) has been received. If a submission is made, the NDSAC reviews the submission and makes a recommendation for scheduling. The recommendation of the NDSAC is posted to the NAPRA website approximately 7 days after the meeting. This triggers the start of a 30-day consultation period during which comments on the interim recommendation of the NDSAC are received by NAPRA. After the 30-day consultation period, the NAPRA Executive Committee makes a final recommendation for scheduling. If Health Canada has already changed the Prescription Drug List, then the National Drug Schedules (NDS) will be changed immediately according to the final recommendation. If the Prescription Drug List has not yet been changed (i.e. it is during the 6 month waiting period), then the

OUTLINE OF THE SCHEDULES [6]

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.

change to the NDS will not occur until Health Canada has updated the Prescription Drug List (after the 6 month waiting period). It is important to note that if no submission to NAPRA is received, the policy for drugs not reviewed will apply and the drug will remain in Schedule I.[7]

To receive updates on NDSAC activities and changes to the NDS, individuals can subscribe to the Drug Scheduling External Liaison Group (DSELG) - http://napra.ca/pages/Schedules/Overview.aspx?id=2396.

Members are reminded that the National Drug Scheduling Advisory Committee does not review drugs that have been given prescription status by Health Canada. These drugs are all automatically considered to be in Schedule I of the National Drug Schedules (NDS). Many of these are listed in the NDS for clarity, but since there is no automated link between Health Canada's databases and the NAPRA National Drug Schedules, it is possible that some drugs that have been classified as requiring a prescription by Health Canada are not captured in the NDS.

Additionally, member can verify the Prescription Drug List and the schedules to the *Controlled Drugs and Substances Act* and its regulations, or Health Canada's Drug Product Database[8], to find out if a drug requires a prescription at the federal level. If the drug has been classified as non-prescription by Health Canada, members are encouraged to utilize the NAPRA National Drug Schedules to determine the current conditions of sale for that drug. However, as drugs are subject to schedule changes, it is important for members to be familiar with the process directing such changes, resources to keep current, and how schedule changes may affect their practice.

REFERENCES

1 Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php
2 Health Canada – Prescription Drug List FAQ. Retrieved at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php
3 Health Canada – Prescription Drug List FAQ. Retrieved at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php
4 Available at: http://napra.ca/pages/Schedules/Search.aspx
5 Available at: http://napra.ca/Content_Files/Files/SupplementalStandardsofPracticellandIII-June2005.pdf
6 National Association of Pharmacy Regulatory Authorities (NAPRA) – Outline of Schedules. Retrieved at: http://napra.ca/Content_Files/Files/Schedules-Outline.pdf
7 NAPRA - Policy for Drugs Not Reviewed. Available at: http://napra.ca/pages/Schedules/Overview.aspx?id=1965
8 Available at: http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

For a quick guide on how to look up something in the NAPRA schedules, watch OCP's e-Learning Module on the Food and Drugs Act (Chapter 7).