Canadian Association of Professionals in Regulatory Affairs/
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Questions from CAPRA Switch Guidance Document Webinar Participants - Feb 20, 2014

1. **You mentioned data requirement for safe and efficacy, are there any requirement for chemistry and manufacturing?**

NHPD Response:

Section 2.2.2 (Additional Requirements for Partial Switch Submissions) mentions chemistry and manufacturing: Additional efficacy and safety evidence must be submitted when the modifications involve a new indication, target population, route of administration, or dose/dosage regime. The types of safety and efficacy evidence that can be submitted are outlined in sections 2.4 and 2.5, respectively. Additional chemistry and manufacturing data will be required when there are changes made to the dose/dosage unit, formulation or dosage form. Information on quality requirements can be found on the Health Canada website in existing guidance for both natural health products (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php) and drugs (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/chem/index-eng.php).

2. **2. Is there any list of products that are being considered to be switched to OTC.**

NHPD Response:

Notices of changes to the Prescription Drug List can be found on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/notice-avis-eng.php

3. **Please provide additional information about the expected timelines to complete post approval switch activities on the PDL.**

NHPD Response:

The process for adding and removing medicinal ingredients from the Prescription Drug List can be found on the Health Canada website in the Questions and Answers document: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php

4. **Comments on how successful applicants are to 1) switches, 2) rationale for not conducting actual use studies.**

NHPD Response:

1) Health Canada does not have data on how successful applicants are with switch applications. 2) When a medicinal ingredient is removed from the Prescription Drug List and a prescription drug is then sold as a non-prescription drug, this non-prescription drug is regulated under Division 8 requirements of the *Food and Drug Regulations*. Product monographs are available for each non-prescription drug on the Health Canada web site. Information related to consumer use studies and actual use studies can be found in these product monographs. Product monographs are not a requirement under the *Natural Health Products Regulations* for natural health products.

5. **Information on trends in switches.**

NHPD Response:

Health Canada does not have information on trends. It is the sponsor's decision to apply for a full switch or a partial switch.

6. **What are the common errors made by sponsors with respect to Rx to OTC switches.**

NHPD Response:

One common error is when a medicinal ingredient is the first of its therapeutic class to be switched in Canada, consumer use studies and actual use studies are performed with a different active ingredient – this is not considered acceptable, even if it belongs to the same therapeutic class. Health Canada encourages sponsors to request a pre-submission meeting to explore the regulatory requirements, ensure an optimal understanding of the data and information requirements, and get answers to specific questions relating to their submission before filing.

7. **Please provide additional details on meeting submission requirements and performing switch evaluations / assessments**

NHPD Response:

Including a cover letter with the switch application is a good idea – in some cases, it is not clear if an application is in fact a switch application.

Health Canada encourages sponsors to request a pre-submission meeting to explore the regulatory requirements, ensure an optimal understanding of the data and information requirements, and get answers to specific questions relating to their submission before filing.

8. **Are switch submissions now expected to be complete within the Management of Drug Submissions target timelines? The current Management of Drug Submissions Policy states that "Rx to OTC - no new indication" will undergo first review in 45 + 180 days. I assume this type of submission would correspond to a "full" switch, and that a partial switch would take the 45 + 300 days of a NDS.**

NHPD Response:

The current Management of Drug Submissions Policy applies to non-prescription drugs but not to natural health products.

Can you please confirm:
• Performance targets for review are as above?

NHPD Response:

Yes, the timeline indicated in the Management of Drug Submissions Policy is correct.

• Do the current review performance targets include the Scientific committee review and endorsement? If not, how long is that expected to take?

NHPD Response:

No. the performance targets does not include the Prescription Drug List Committee review and endorsement time. The process for adding and removing medicinal ingredients from the Prescription Drug List can be found on the Health Canada website in the Questions and Answers document: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php

• Will there be performance targets for evaluating the comments received during the consultation?

NHPD Response:

Health Canada makes every effort possible to review the comments as efficiently as possible.

9. **If there is an OTC use for a new drug already approved ie. ketoconazole shampoo – what would be required for another OTC use to be approved ie. face wash for acne control? Is this considered a partial switch?**

NHPD Response:

Switch submissions are only for prescription to non-prescription changes. A non-prescription drug on the Canadian market coming in for a different indication is not considered a switch.

For any medicinal ingredient which has not been authorized previously in Canada for the proposed indication or intended population or direction of use; the safety and effectiveness of that medicinal ingredients under the conditions of use has not been established. As such, in accordance with section C.08.001 (b) of the *Food and Drug Regulations*, the proposed product is considered a New Drug. Full data on efficacy, safety and chemistry will be required.

10. Would like to have case studies for successful switches in Canada

NHPD Response:

Health Canada does not have case studies. However, with respect to consumer use studies, information related to these can be found in non-prescription drug product monographs.