CAPRA LABELLING SYMPOSIUM

PLAIN LANGUAGE LABELLING WORKSHOP

WORKSHOP OUTLINE

The Plain Language Labelling (PLL) Workshop will be held on Day 2 of the Symposium, and will be facilitated by the CAPRA Symposium Planning Committee in conjunction with the PLL presenters from Health Canada and industry.

During the PLL Case Study Workshop session, each table will be assigned **one** of the five enclosed case studies to discuss as a small group. Each table should designate a scribe to document the group's responses to the questions within your assigned case study.

During the Plenary Session, all five case studies will be discussed with the Symposium attendees and speakers. Each group will be asked to **briefly present** their proposed responses to the questions within their assigned case study.

A subsequent PLL Panel Discussion/Q&A will also be held, as an opportunity to ask the PLL speakers any additional questions, including for PLL topics not covered within the case studies.

Case study #1 – SNDS in Response to Advisement Letter

An Advisement Letter is received by a Sponsor requesting updates to the Product Monograph for a prescription drug. No changes were proposed to the outer or inner labels. The Sponsor has evaluated that the requested changes are significant as they affect several sections of the Product Monograph (PM) and the Package Insert (PI), as the PI is identical to Part 3 of the PM. The Advisement Letter requests that the changes be submitted in the form of an SNDS within 30 days.

The Sponsor/Manufacturer is a Canadian affiliate of a global company. The Global Company has internal processes that must be followed requiring that any changes to labelling must be approved by a cross-functional team of Global experts. Typical internal timelines to secure approval for labelling changes and preparing regulatory submissions are as follows:

- Global to approve label changes15 calendar days for rush reviews (typically two rounds of review ensue between Canadian reviewers and Global expert reviewers).
- Translation for rush jobs – 5 working days
- PI mock-ups for rush jobs – 20 working days
- Centralized regulatory publishing – 5 working days

Total: 45 days - using an accelerated timeline

The Canadian affiliate realizes that with PLL requirements for SNDS filings (e.g. French language and mock-ups), the 30 days requested submission timeline cannot be met.

Questions:

1. What approaches can the Sponsor take to meet the 30 day submission timelines?

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2. What options may Health Canada suggest?

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Case Study #2 – Outer Label Challenges

A new, lower tablet strength of an already approved prescription drug was submitted for review. The review of the outer drug bottle label for this new strength noted a few elements that were not aligned with PLL requirements (listed below).

Question: For each issue what approaches can the Sponsor take to address Health Canada's comments in light of their realities?

1. **Health Canada comment:** Expiry date format of MM-YYYY (all in numbers, e.g. 11-2016) is not one of the acceptable formats.

   Company perspective: The expiry date format is the Global standard for all bottles and blister drug products packaged at this manufacturing site. The equipment used on the manufacturing line to stamp on the expiry date is also connected to other variable text stamping like the LOT number. Thus, the equipment for stamping on the LOT and expiry information is linked together, well-established and changes in the expiry dating format requires re-tooling, testing and validation, which will take at least 12 months, if undertaken.

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2. **Health Canada comment:** Internal reference numbers linked to the product and label specimens should be removed.

   Company perspective: The numbers are unique and version identifiers for the label components are manufacturing site requirements as they support in-process and document control, and traceability procedures.

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3. **Health Canada comment:** The bottle label font size is 4.5.

   Company perspective: Due to the relatively small bottle label size, re-sizing all the text to 9 pt. font does not fit. To keep all the text on the bottle, the maximum font size possible is 6 pt., but white space is still minimal.

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4. **Health Canada comment:** To eliminate unnecessary text, remove the trademark information as it is not required by the regulations, nor is it considered essential information for the consumer.

   Company perspective: There are mandatory Company requirements to maintain trademark information on any printed material related to a product and/or Brand in order to prevent the copying or imitation of these materials, in support of product security and anti-counterfeiting measures.

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Case study #3 – Change in Tradename During Review

When filing a NDS or SNDS mock-ups are required at the time of submission. A majority of tradenames used by Sponsor's are typically global in nature to assist with brand identification and reduce confusion in the global marketplace. As discussed the Look-Alike Sound-Alike (LA-SA) requirements must also be fulfilled in the submission.

Challenge occurs with tradenames when there are simultaneous submissions globally (i.e. Health Canada, FDA, EMA) and a Health Authority rejects the tradename. This would then require the filing of new LA-SA supporting documentation and mock-ups during the review. Specific to the PLL requirement for updated mock-ups, this can often create a great deal of work for changing just the tradename such as: new manuscripts, translation, proof-reading, graphic artist support and refiling in eCTD.

NOTE: Regarding mock-ups, simple one word or one sentence changes would also fall into the same issue.

Questions:

1. What would be the best option for the Sponsor to address this PLL requirement?

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2. What are the alternatives that Health Canada could consider regarding changes such as this?

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Case study #4 – Mock-Up Labels and Product Line Extensions

A manufacturer is currently approved for a solid oral dosage form that is available in one strength.

The approved strength was reviewed and approved prior to the PLL Regulations coming into force. As such, only text labels were submitted and approved. Market notified labels have yet to be provided to Health Canada.

The manufacturer has now filed a supplemental drug submission to seek approval for an additional strength. The filing date for this submission is after the new PLL Regulations coming into force.

During the review of the mock-up labels, substantial design changes were requested of the manufacturer, including design changes that may impact the labelling for the existing approved strength.

Questions:

1. How should the Sponsor respond to Health Canada's PLL review of the mock-up labels within the context of this submission?

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2. What next steps should the Sponsor undertake with respect to the labels for the currently approved strength?

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3. What should Health Canada take into consideration when reviewing mock-up labels within the context of product line extensions?

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Case study #5 – Identifying an Alternate Approach to Meeting Font Size Requirements

A manufacturer has filed a New Drug Submission for an oral tablet that comes in 3 strengths. The tablets will be packaged in small bottles that contain 7, 30 or 90 tablets. No outer carton was proposed.

The font size on these bottles is at 3.75 points, which does not meet Health Canada's minimum font size of 6 points for small containers or special containers. In addition, the bottle does not meet the small container requirements, because there is no outer label that contains all of the text required by the *Food and Drug Regulations.*

The sponsor and Health Canada have worked together to eliminate any unnecessary text and to re-arrange some of the information on the label and now the font size is at 5.25 points, which still does not meet the minimum font size.

Questions:

1. What can the sponsor do to increase their font size?

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2. What creative option(s) might the sponsor utilize to have their bottles be considered a small container as per the regulatory requirements?

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3. What other approaches might the sponsor take?

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4. What other options might Health Canada suggest?

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