Regulatory Essentials – May 30, 2018

Health Updates

Revised Fee Proposal for Drugs and Medical Devices

In April 2017, Health Canada communicated its intent to update fees and began its engagement process with stakeholders with the public consultation in October. After analyzing all the comments received from the consultation Health Canada revised the Fee Proposal following five guiding principles:

- Be Reasonable and Fair: recognizing that industry needs to pay its fair share and reduce the burden on taxpayers, fees have been set reasonably and are being phased-in
- Minimize Impact on Small Business: fees should not deter small businesses from doing business in Canada
- Apply Appropriate Mitigation and Fee Waivers: fees should be reduced or waived in explicit circumstances to support the health care system
- Make Fee Increases Gradual and Predictable: fees will be phased-in over multiple years
- Ensure Accountability: remaining transparent and accountable to stakeholders through annual reporting and annual engagement is key to developing an agile and responsive fee framework

Cosmetics Alliance appreciates and supports these key guiding principles as they reflect the spirit of the commentary and address the base concerns that was outlined in CA's original commentary. In this regard we welcome the revisions for the proposal and the opportunity to be engaged. The revised proposal is a positive process that provides another opportunity to engage additional commentary on the revised proposal. The proposal has been substantively revised, and it reflects sound consideration of most of our initial feedback. CA is pleased that Health Canada is open to refining their approach and we have another 'kick at the can' to provide constructive feedback. Our engagement in the revised proposal is critical as its clearly made a difference.

Cosmetics Alliance has reviewed the Revised Fee Proposal and created a comparison chart outlining the key fee changes from the original Fee Proposal for Drugs and Medical Devices.

The key points form the Revised Fee Proposal:

- Introduced a four-year phase-in period, with no annual fee increase greater than 25% for PME & EL fees
- Annual Increase based on CPI (Consumer Price Index) has not changed
- Revised fee setting ratio to 75% for Pre-Market Fees for Drugs and Medical Devices
- Revised fee setting ratio to 67% for all Right to Sell Fees
- Expanded fee relief for small business

WebEx and Feedback Form – Revised Fee Proposal for Drugs and Medical Devices

Please take the time to review the Revised Fee Proposal. Health Canada will accept the feedback on the Revised Fee Proposal until June 14, 2018 via an online form. Please also send a copy of your feedback to Cosmetics Alliance at regulatory@cosmeticsalliance.ca.

When filling out the feedback form, Health Canada indicated that:

- Feedback must be provided via this form to be considered.
- Each specific issue requires a separate feedback form.
- Feedback is being solicited on the following subjects: Fee Setting, Annual Fee Adjustment, Small Business, Mitigation Measures, Performance Standards, Penalty Provision, Timing of Payment, and Specific Fee Line changes.

We welcome any additional commentary on any related matters and would encourage these also be shared with Health Canada, as appropriate.

In the interim, Health Canada will be hosting a Webex for stakeholders to give an opportunity to seek clarification on the Revised Fee Proposal. Cosmetics Alliance will be participating in this Webex and we encourage members to register for this session as well.

WebEx Details:

To join the **English WebEx** on June 1, 2018 from 1:30 p.m. to 3:30 p.m., please register through WebEx in advance of the event.

Topic: Cost Recovery

Date and Time:

Friday, June 1, 2018 1:30 p.m., Eastern Daylight Time (New York, GMT-04:00)

Event number: 559 750 436

Event password: costrecovery

Teleconference information (Please use the CALL ME feature)

Participants:

Toll-free dial-in number (Canada/US):1-866-805-7923

Local dial-in number: 613-960-7518

Passcode: 3636789#

For assistance

1. Go to https://gts-ee.webex.com

2. On the left navigation bar, click "Support".

3. Call 1-800-226-6338 or 613-941-9554

IMPORTANT NOTICE: This WebEx service includes a feature that allows audio and any documents and other materials exchanged or viewed during the session to be recorded. You should inform all meeting attendees prior to recording if you intend to record the meeting. Please note that any such recordings may be subject to discovery in the event of litigation.

To join the **French WebEx** on June 1, 2018 from 11:00 a.m. to 1:00 p.m., please register through WebEx in advance of the event.

Topic: Cost Recovery

Date and Time:

Friday, June 1, 2018 11:00 am, Eastern Daylight Time (New York, GMT-04:00)

Event number: 551 621 653

Event password: costrecovery

Teleconference information (Please use the CALL ME feature)

To receive a call back, provide your phone number when you join the event, or call the number below and enter the access code.

Call-in toll-free number (Canada/US): 1-877-413-4781

Call-in number: 1-613-960-7510

Attendee access code: 649 749 8

For assistance

1. Go to https://gts-ee.webex.com

2. On the left navigation bar, click "Support".

3. Call 1-800-226-6338 or 613-941-9554

Revisions of DEL Guidance Documents

On May 22, 2018, Health Canada released notice outlining revisions to Drug Establishment Licensing Guidance Documents and Forms because of Amendments to the Food and Drugs Regulations. The GUI-0002 has been updated and the key points are highlighted below. Please take the time to review the guide and let your CA Regulatory Team know if you have any questions at regulatory@cosmeticsalliance.ca.

Highlights

- Implementation date: May 17, 2018
- New PDF-Fillable DEL Application Form https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033-eng.pdf
- New Table A issued
- Updated clarity on Assembling Kits and Promotional Material
- Added clarity on *testing exceptions* for fabricators & packagers/labellers (both domestic and foreign), distributors and importers. This is important from fee schedule perspective.
- New details for *package/label for fabricators* exception
- New details for *label for importers* exception
- Updated clarity on when fees are to be paid

- Updated clarity on drug analysis fees

Plain Language Labelling Flexibility Requests

Health Canada has asked at the May 25, 2018 Drug PLL Lessons Learned Session for industry to propose additional flexibilities on the two requests below:

1. Request for Font styles by June 15, 2018. The Good Label and Packaging Practices Guidance Document is currently being revised and Health Canada is taking this opportunity to make this ask for inclusion of acceptable fonts as part of the font repertoire.

- Your submissions need to be supported by evidence of legibility
- Health Canada has indicated Calibri is not supported as an option to be added since it does not have a Condensed style

We are working with Health Canada to determine the most appropriate mechanisms for submitting this information. We will keep you informed as this item progresses. In the meantime, members should work with their agencies / label developers on creating your list of fonts along with the supporting evidence.

2. Canadian Drugs Facts Table Heading Request

Industry to propose revisions to the CDFT headings by June 15, 2018. The Good Label and Packaging Practices Guidance Document is currently being revised and Health Canada is taking this opportunity to make this ask for inclusion of the use of different words instead of those currently used.

- Stakeholders have indicated the headings are too long and not representative in French
- Consistent headings must be maintained, however different words may be considered instead of those currently used

We have created a template for your use in compiling your recommendations, we strongly suggest adding in a rationale and, if you have one, reaching out to your translators for assistance in compiling the French lists.

We will prepare an aggregate submission from responses we receive. Please send your recommendations to regulatory@cosmeticsalliance.ca by **June 12th.**

Annual and Quarterly Drug Submission Reports

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of the pre-market drug review process against target performance standings (see MDSG Appendix 3). The annual report for TPD and BGTD compares five consecutive fiscal years (April 1 - March 31) from 2013-14 to 2017-18 and the annual report for NNHPD compares four consecutive fiscal years (April 1 - March 31) from 2014-15 to 2017-18. The quarterly report compares five consecutive quarters from January - March 2017 to January - March 2018.

Annual Drug Submission Reports:

Therapeutic Products Directorate

Biologics and Genetic Therapies Directorate

Natural and Non-Prescription Health Products Directorate

Quarterly Drug Submission Reports:

Therapeutic Products Directorate

Biologics and Genetic Therapies Directorate

Natural and Non-Prescription Health Products Directorate

Environment Updates

Notice of the Publication of the Microbial Identification Framework for Risk Assessment

On May 18, 2018, the Government of Canada released the Microbial Identification Framework for Risk Assessment (MIFRA) which provides guidance on the information required for identifying micro-organisms notified under the New Substances Notification Regulations (Organisms). It is a detailed technical document intended to help notifiers with the choice of methodology and the analysis of scientific data required for adequate microbial identification. Cosmetics Alliance is aware that this may not be significant for most membership however we advice any stakeholder using organisms to review the MIFRA.