

May 23, 2018

Fee Proposal Teleconference with Health Canada

Health Canada invited Associations to participate in a teleconference to update stakeholders on the progress on the Fee Proposal for Drugs and Medical Devices first published in October 2017. Health Canada has reviewed all industry feedback and would like to present a revised and compromised proposal.

For this call, CAPDM, NPAC and Direct Sellers Association were invited.

Health Canada is planning to publish a revised Fee Proposal (approximately 50 pages) by the end of this week or early next on the HC website.

There will be a 15-business day time period for feedback using a Health Canada template. There should be one issue per template. Approximately one week after the publication has gone live on the Health Canada site, there will be a WEBEX offered to review the document and clarify any issues with stakeholders. An email will be sent to industry stakeholders with information.

Following this feedback process, Canada Gazette 2 will be published in December 2018, with an anticipated effective date of April 2019.

For the purposes of this call and the related stakeholders, only relevant sections of the Fee Proposal were reviewed.

Pre-Market Fees:

- Reduced to 75% of cost recovery versus the original 90%
- Implemented over 4 years with no annual fee increase >25%
- CPI increase after first year

Right to Sell:

- OTC's and Disinfectants will be removed from the list of Prescription products at \$4500
- OTC's will be charged at \$2700 to reflect the lesser risk
- Disinfectants will be charged at \$1400 to reflect the lesser risk
- Implemented over 4 years with an annual increase capped at 50%
- There will be no fee for dormant DINs

Establishment Licences:

- 100% cost recovery remains
- To be phased in over 4 years as opposed to immediately
- No annual increase to exceed 25%
- CPI increases to be added after first year

MISC:

- Small Business (if you meet the definition), all pre-market submission costs will be cut in half. The cap of \$10,000 will be removed.
- First Establishment License will be pro-rated depending on the time of year application is made.
- Health Canada Performance Standards have not been changed.

ACTION ITEMS:

1. CAPDM will participate in the WEBEX
2. CAPDM will mobilize the Regulatory Advisory Group to respond to the proposed fee proposal once published
3. CAPDM will disseminate relevant information to members.