

SUMMARY: Meeting with JUUL Labs

Subject: Vaping Products

Date: 2018-08-13

Participants:

Health Canada (HC)

Denis Choinière
Director, Tobacco Products Regulatory
Office, Tobacco Control Directorate (TCD)
(Chair)

(by teleconference)
Senior Manager, Tobacco and Vaping
Compliance and Enforcement Program
(Ontario Region)

Senior Policy Advisor, Director general's
office (TCD)

(by teleconference)
Manager, Tobacco and Vaping Compliance
and Enforcement Program (Ontario Region)

Geoff Barrett
Director, Risk Management Bureau,
Consumer Product Safety Directorate
(CPSD)

JUUL Labs:
Lise Jolicoeur
Director, Public Affairs, StrategyCorp

Manager, Office of Research and
Surveillance (TCD)

Mike Nederhoff
General Manager, JUUL Canada

Manager, Office of Research and
Surveillance (TCD)

Gal Cohen
Senior Director, JUUL Labs

Manager, Risk Management Bureau (CPSD)

Eric Omwega
Director, New Markets Development, JUUL
Labs

Senior Policy Analyst, Office of Policy and
Strategic Planning (TCD)

Introduction:

A meeting was held at the request of JUUL Labs (JUUL) to discuss Canada's ongoing regulatory process and to talk about their upcoming market expansion to Canada.

The Chair opened the meeting by doing round table introductions. The Privacy Key Messages were read and acknowledged.

In addition, in the interest of transparency, the department stated that the meeting is subject to disclosure as per Health Canada's Openness and Transparency Policies. Therefore, nothing

shared during this meeting is considered confidential and personal information may be disclosed without further consent.

Subjects:

JUUL provided an overview of its current market presence: it currently sells products in the US, Israel, and the UK. JUUL indicated that it is looking to expand to Canada imminently. It wished to wait for the new regulatory framework to be established with Royal Assent of Bill S-5. JUUL further stressed that it wishes to ensure it complies with the new legislation, and intends to market its product for recreational use.

HC asked whether JUUL was looking at marketing its products going forward as nicotine-replacement therapy. JUUL responded that its initial focus in the US has been consumer-based - getting smokers to switch to vaping. However, it also indicated that it is working with the FDA to investigate the use of JUUL in clinical trials as a cessation tool.

HC asked JUUL whether the nicotine content of its JUUL pods exceeds the standard in the EU, and if so, whether the vaping liquid has been reformulated for sale in the UK. JUUL answered that their vaping liquid has been developed in varying nicotine strengths as they are aware of and respectful of regulations in each jurisdiction it intends to introduce products in. For commercialization in Canada, JUUL intends to introduce 5% nicotine vaping liquid, which is similar to the product offered in the US, and then offer lower nicotine content products for those who wish to taper.

HC asked JUUL whether it is studying the use of lower dose products as a means of titrating users. JUUL responded that it is looking at trials that study puff topography, satisfaction, and switching. It recognizes that each individual user has their own set point. Studies are still underway.

HC remarked that the cartridges currently on the market are pod-based and not refillable, and asked whether JUUL intends to make refillable cartridges. JUUL answered that they are focusing on the “closed system” due to its ease-of-use and end-to-end consistency. JUUL further explained that while the devices were designed in the US and are manufactured by a contract manufacturer in China, the vaping liquid is designed and manufactured in the US for quality control purposes.

JUUL indicated that it is continuing to develop its devices to include a processor that would provide computing power for digital integration, user validation, and function as a technology platform. HC asked if the device’s technology could be leveraged to monitor use of the device. JUUL answered that it could be possible to do so, and that its next generation of devices would include registration functionality such that only the user could use the device.

HC asked if the immediate focus for marketing its products in Canada included nicotine-containing products. JUUL confirmed that they are exclusively focused on nicotine-containing products at this time.

HC asked JUUL which retail channels it plans to use to sell its products in Canada. JUUL responded that it wishes to make its products available where adult smokers purchase cigarettes, such as convenience stores. JUUL also intends to sell its products at specialty shops, such as vape shops. JUUL would import its finished goods into Canada for distribution.

HC asked JUUL about the recent statement from the FDA regarding use and access by youth of e-cigarettes, including JUUL, and what its plans were for Canada with respect to youth access. JUUL clarified that the FDA was targeting retailers in its enforcement “blitz”, such as online retailers like e-bay, and it is not targeting JUUL specifically. JUUL also indicated that it has an active surveillance program in place for online sales via its platform, whereby a purchaser must undergo several layers of identification. It also has its own secret shopper program for third-party retailers and distributors. With respect to sales in Canada, JUUL confirmed that it is aware of the sales to youth prohibition in Canada. It intends to offer online sales in Canada, except Quebec (where only in-person transactions are permitted). It plans to use a third party data verification company in Canada, and will require proof of identification at delivery.

HC asked JUUL if it does surveillance for incidents. JUUL responded that incidents are reported to the company through its customer service line. Consumers can call or email for quality-related issues.

JUUL asked how it could work best with HC. HC stated that there is less collaboration with respect to the regulatory process. However, the Consumer Product Safety program would be a good first point of contact with respect to health and safety issues. HC also indicated that it would be helpful to establish a relationship with compliance and enforcement staff. With respect to surveillance, it would be helpful to be aware of the timing of new products so that JUUL could be included in surveillance tools. With respect to science, it would be helpful if JUUL could send studies or data that HC should be aware of.

JUUL asked if HC had any concerns with its upcoming market entry. HC responded that JUUL would need to ensure compliance with the *Tobacco and Vaping Products Act* and the *Canada Consumer Product Safety Act*.

Conclusion:

The meeting was then concluded.

Documents:

N/A