Meeting summary - November 18-19, 2019: Scientific Advisory Board on Vaping Products

Attendees
Dr. Carolyn Baglole
Dr. Linda Bauld
Dr. Maciej Goniewicz
Dr. Lorraine Greaves
Dr. David Hammond
Dr. Steven Hoffman (Chair)
Dr. Andrew Pipe
Dr. Rachel Tyndale
Mr. James Van Loon (Executive Secretary)
Dr. Kenneth Warner

Regrets
Dr. Geoffrey Fong

Invited Guests (Tues)
Dr. Stephen Robbins
Ms. Ebele Unaegbunam

Secretariat
Mr. Adam Doane
Ms. Fatima Mussa
Ms. Amy Wilson
Ms. Amanda Lye

Observers/Presenters
Dr. Gordon Barrett
Ms. Rachel Bennett
Ms. Brooke Campus
Mr. Mathew Cook
Ms. Christine Czoli
Mr. Matthew Gagne
Ms. Ivana Kosarac
Ms. Kristin Macey
Mr. Rob Nugent
Ms. Pamela Ponic
Ms. Holly Stardom
Ms. Megan Tam

Meeting Summary

1. On November 18-19, 2019, members of the Scientific Advisory Board (SAB) on Vaping Products met in Ottawa for their fifth meeting. The agenda is attached in Appendix I.

2. On the first day, the Chair of the SAB, Dr. Steven Hoffman, welcomed participants and provided an overview of the agenda. In his introductory remarks, Dr. Hoffman noted the rapid pace of change in the six months since the previous meeting. The introduction was followed by a brief roundtable. The agenda was revised at the request of a board member in order to accommodate another commitment.

3. Mr. Van Loon presented on two pressing issues, specifically trends in youth vaping and the recent emergence of vaping-associated lung illness (VALI). Health Canada provided a detailed account of the cases of VALI in the United

States and Canada, as well as emerging findings from the public health investigation about the role of certain products and chemicals of concern. Health Canada described the activities underway to monitor and respond to VALI, and Mr. Van Loon summarized the range of regulatory and non-regulatory tools available to Health Canada to respond, both in the context of nicotine and cannabis vaping. Turning to youth vaping, Mr. Van Loon recapped the most recent evidence available on youth vaping trends in Canada and the United States, touched on regulatory measures and proposals being pursued at state, provincial and federal levels across North America, and then reviewed a variety of non-regulatory measures the department has pursued alongside the regulatory agenda, including communications, public education, partnerships and grants, and research. Following the presentation, the board initiated discussion on a number of issues, including:

- Opportunities for alignment between the federal regimes for cannabis and nicotine vaping products
- The need for improved understanding of product composition and quality (and how absence of product standards is makes it difficult for health professionals to support of vaping as an alternative for smokers)
- Increases to minimum age being implemented in the US
- Issues related to nicotine limits
- Ways in which youth are accessing vaping products and the impact of cross-border commerce
- Methodological differences in how vaping product use is measured across jurisdictions
- Some panel members expressed views that greater regulation of the content of vaping solutions and devices was needed, including the prohibition of flavours

4. Dr. Carolyn Baglole presented on vaping and lung health. Dr. Baglole reviewed the historical context of pulmonary diseases caused by tobacco products, and then explored the current case reports related to vaping in the medical literature, as well as potential pathogenic mechanisms. The presentation conveyed the diversity of manifestations of pulmonary health effects in the available case reports (including lipoid pneumonia, hypersensitivity pneumonitis, respiratory bronchiolitis, organizing pneumonia, idiopathic pulmonary fibrosis, acute eosinophilic pneumonia), and the challenges created

by varying exposures, products, diagnoses, susceptibility and risk factors. A key message was that research needs to contemplate how the health risks from vaping may be distinct from the known risks of smoking and tobacco use. The latter section of the presentation focused on cannabis and the research program being initiated at McGill to examine the impacts of inhaled cannabis on lung health. The subsequent discussion addressed matters including exogenous vs. endogenous lipoid pneumonia, and the substantial challenges posed by vaping product variability, user behaviours and latency in the onset of disease. Differing viewpoints were expressed on VALI and whether it represents an emergent or underlying phenomenon. This led to discussion about the ability of different health systems to detect emergent diseases, including in the UK where, despite a single National Health Service and high prevalence of vaping, outbreaks of VALI have not been detected. A discussion about differences between vaping products and vaping product regulations in different jurisdictions then followed. A question was raised about whether a meeting of specialists and experts in relevant disciplines might be convened to debate the accumulated evidence on health effects, with an aim to improve the understanding of health consequences of using vaping products.

5. Health Canada provided a series of 3 short presentations. The first provided a summary of chemical analyses that Health Canada has undertaken on a large sample of vaping liquids from the Canadian market, and tools and approaches that can be used to identify substances of potential concern. Health Canada then presented on the challenge posed by chemicals that lack toxicological data, and how the anticipated level of exposure and inferences based on broad chemical classes might be used to prioritize these substances for additional study. The third presentation highlighted findings related to sweeteners, illustrating how these chemicals overlap across flavour categories and emphasizing recent studies that have investigated the role sweet flavours play in product appeal and the reinforcing effects of nicotine. The board discussed the limitations in the existing toxicological database for identified constituents and hazard classifications (paucity of inhalation and/or long term studies, challenge of interactions between chemicals). The conversation returned to issues of product composition and quality, leading to a suggestion that ingredients be reported to the regulator and that simple quality measures (e.g. requiring USP grade ingredients) be pursued.

6. Health Canada then presented on the responses to a consultation held in Spring 2019 on potential regulatory measures to reduce youth access and the appeal of vaping products. The consultation, which focused on six areas (flavours, nicotine, design, retail access, packaging, regulatory transparency), was open for a 45-day period and Health Canada received over 24,000 responses. The presentation also highlighted recent federal, provincial/territorial, state and local initiatives that had been enacted or announced related to each of the topics. For example, shortly before the SAB meeting the government of British Columbia announced proposed measures relating to flavours, nicotine, retail access and packaging. Given the close connection to the subsequent presentation on patterns and trends in youth vaping, discussion was deferred until after Dr. Hammond's presentation.

7. Dr. Dave Hammond presented on trends in vaping among youth. He shared some recent data on vaping among youth in Canada, the United States and England from a prospective cohort study. The data show growing rates of use among youth, as well as increasing frequency of use among youth vapers between 2017 and 2019. He also presented data that suggested changing brand preference among youth vapers. Dr. Hammond provided data at the provincial level, noting that self-reported exposure to advertising was lower in provinces with stronger promotional restrictions, and higher in provinces with fewer restrictions. There was discussion about these data and their value in permitting comparisons in patterns and trends in the US, Canada and the UK, and how the breakdown of results across and within countries allows for natural experiments to be exploited. Key messages from Dr. Hammond included: that the relationship between youth prevention and adult switching is not 'zero sum'; that the current situation was detrimental to both youth and to adult smokers; and that measures on vaping should be coupled with aggressive measures on smoking. SAB members discussed the differences between vaping in Canada and the United Kingdom, and it was noted that in the United Kingdom the societal perception of vaping products is different, possibly because they have been consistently promoted as a smoking alternative intended for adult smokers.

8. A representative from Health Canada presented on patterns and trends in the market for tobacco and vaping products. Health Canada presented data on

tobacco sales across Canada reported under the *Tobacco Reporting Regulations* including newly-available data through mid-2019. These data indicate a continuing decline in the cigarette sales volumes, broadly distributed across the country. Potential drivers for the decline were discussed, and it was further noted that despite declining volumes, the wholesale value of the cigarette market has risen due to industry increases in wholesale price. The second segment of the presentation focused on the vaping market, using information from AC Nielsen and Euromonitor. These sources suggest growth of the overall vaping market to approximately $900M in 2019, with an expansion of gas and convenience stores from a negligible value to now represent approximately 40% of the total market. AC Nielsen data for gas and convenience channels through August 2019 suggest that JUUL now accounts for three-quarters of market share in this channel, and Vype comprises most of the remaining quarter. Research questions were raised, centering on drivers for both the decline in cigarette sales and growth in the vaping market and the extent to which smoking cessation, vaping products, and price have played a role in recent market changes. The SAB discussed a variety of topics, including the retail channels through which youth are obtaining vaping products, the impact of price and price differentials on consumer behavior, and how the growing market share should create a growing obligation for companies to provide evidence on safety and effectiveness.

9. The second day of the meeting opened with a brief welcome by the Chair and review of agenda for the morning.

10. Dr. Hoffman presented on vaping in the global context, with a focus on different types of policy instruments currently used in countries around the world to address vaping (such as prohibition, regulation, component bans, sales restrictions, taxation, and subsidization, etc). Dr. Hoffman also discussed public perceptions of vaping and the role of societal values in determining which measures might be used to address vaping. He noted that various jurisdictions need to consider multiple factors (including demographics, values, epidemiological data, existing regulations, etc) in order to develop an effective and appropriate policy response. The ensuing discussion was wide-ranging, and included suggestions that there would be benefit to dedicating time to exploring the values and beliefs that underpin recommendations, that health

disparities across countries confound the notion that harm can be easily quantified, that the model would benefit from incorporating other products (e.g. cessation pharmacotherapies), and that smoking be considered alongside vaping in the discussion of policy stances, incentives, and disincentives.

11. Dr. Andrew Pipe presented on the role of e-cigarettes in smoking cessation. He discussed the highly addictive nature of nicotine and the negative impacts of cigarette smoking on individual health and the health care system. He noted that there is a lack of focus on the high risk group of individuals who are already in contact with the health system because of their tobacco use. Dr. Pipe discussed the Ottawa Model for Smoking Cessation and its success in reducing health care utilization and risk of death. He noted the potential benefits of e-cigarettes as a smoking cessation tool and the need for evidence on efficacy and effectiveness for clinicians, as well as clear guidelines and information on the use of e-cigarettes for smoking cessation. Dr. Pipe also expressed his concern that the potential for e-cigarettes to be used as a smoking cessation tool has largely been compromised as a consequence of: the absence of regulations on the content, design and construction of vaping products; adverse publicity surrounding their use and recent emergence of acute lung illnesses; and the admonitions of editorialists and health organizations that clinicians should not advise vaping to their patients. The presentation also highlighted commonalities in industry tactics between the tobacco and vaping industries. Discussion among SAB members centered around clinical settings and clinical research, with several members highlighting the challenges they have faced obtaining approval for clinical trials on vaping, both from institutional ethics boards and from regulators.

12. SAB members provided advice to Health Canada on activities that should be prioritized in light of the rise in youth vaping and the recent cases of vaping-associated lung injuries. It was recommended that Health Canada require manufacturers to fully disclose all ingredients in vaping products to Health Canada.

13. SAB members discussed the need for research evidence on vaping and identified some areas for future research, with an emphasis on research priorities that are specific to the Canadian context. Dr. Hoffman opened the discussion and welcomed representatives from the CIHR Institute of Cancer Research and the CIHR Institute of Circulatory and Respiratory Health who joined by phone. Input was sought from the SAB on a draft commentary on

health research priorities on vaping for the Canadian context that had been prepared in advance of the meeting. Board members were invited to provide their perspectives and insights on areas of research that are context dependent, with the overall aim being better coordination of research efforts and efficient investment in research. Some of the areas noted included:

- Cohort studies that are inclusive of other substance use and risk behaviours
- Understanding impacts of various provincial and territorial policies and regulations through policy evaluations and studies that exploit natural experiments
- Clinical trials to assess efficacy and effectiveness of vaping products as a smoking cessation tool, and the opportunities to conduct research in high-risk subpopulations
- Greater access to data, including Government data holdings, and support for extramural researchers to analyze those data

It was noted that research on vaping must apply both an equity lens and a sex and gender lens throughout, and that there is also an opportunity to focus on community-based research. The source of funding was discussed with specific emphasis on the dilemma of industry-funded clinical research, which is required for therapeutic product applications and tobacco pre-market authorization in the US, but also raises concerns about credibility and conflicts of interest. SAB members discussed the potential for international research collaborations, for example with the United States.

14. In closing, Dr. Hoffman and Mr. Van Loon reflected on the fifth SAB meeting, summarized key takeaway messages, and thanked the presenters. The SAB confirmed that the sixth meeting will take place on May 26-27, 2020 in Vancouver. It was noted that the next meeting will mark the end of the first three-year term, therefore it will be an opportunity for members to reflect on the mandate, scope and membership of the SAB. Dr. Hoffman adjourned the meeting and thanked the board for their efforts.

Appendix I – Meeting Agenda

Scientific Advisory Board (SAB) on Vaping Products

Meeting #5 – November 18 & 19, 2019

Day 1

8:30-10:15 - Introduction

- Welcome - Chair: Dr. Steven Hoffman
- Brief introductions/Roundtable - All
- Health Canada Updates - James Van Loon
- Presentation by Dr. Carolyn Baglole - Vaping and lung health

10:15-10:30 - Break

10:30-12:15 - Identifying and assessing potential sources of health risk

- Presentation by Health Canada

12:15-1:15 – Lunch

1:15-2:45 - Patterns and trends in the use of tobacco and vaping products

- Presentation by Health Canada
- Presentation by Dr. David Hammond - Vaping among youth

2:45-3:00 – Break

3:00-4:00 - Patterns and trends in the market for tobacco and vaping products

- Presentation by Health Canada

Day 2

8:30-9:30 - Global perspectives

- Presentation by Dr. Steven Hoffman - Vaping Regulations in a Global Context
- Group discussion

9:30-10:15 Patterns and trends in the use of tobacco and vaping products

- Presentation by Dr. Andrew Pipe – Smoking Cessation – concerns from a clinical perspective

10:15-10:30 - Break

10:30-11:00 - Deliberation and formulation of advice

11:00-12:00 - Research needs in Canada

12:00-12:15 - Conclusion and Next Steps