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Mr. Katsunobu Kato, Minister of Health, Labor and Welfare 17 September 2019

Mr. Manabu Sakuta, Chairperson, Japan Society for Tobacco Control

1) Around the world, many victims are appearing with severe pneumonia and convulsions from using e-cigarettes and heated tobacco.

2) Please inform doctors nationwide, collect data, and start researching cases.

3) Please inform and warn the public about this situation.

## Chronicle

Multiple cases of severe pneumonia caused by heated tobacco have been reported in Japan.<sup>1,2</sup> In the United States, hundreds of cases of severe pneumonia have been reported, causing some deaths, from electronic cigarettes. In response, the Alberta Health Authority in Canada has issued the following message:

5 September 2019 Subject: Severe Pulmonary Disease Associated with E-Cigarette Use, Surveillance and Notification

To: family physicians; emergency room physicians and staff; nurse practitioners; local health authorities, tobacco control specialists

From: Dr. Digby Horn, on behalf of Medical Officer of Health-Central Zone, Canada

You may have heard of reports of cases of severe lung disease in the United States that appear to be associated with a history of vaping.<sup>(\*)</sup> While there have not been any similar cases reported in Canada to date, effective September 4, 2019, the Chief Medical Officer of Health of Alberta has made severe pulmonary disease associated with e-cigarette<sup>(\*)</sup> use notifiable under the Public Health Act. As a result, any cases meeting the following definitions are required to be reported to the Central Zone Medical Officer of Health (CZMOH) on call, (phone number  $\bigcirc$   $\bigcirc$ ).

## **Confirmed Case**:

A: Using an e-cigarette ("vaping") or "dabbing" in 90 days prior to symptom onset; ANDB: Pulmonary infiltrate, such as opacities on plain film, chest radiograph or ground-glass opacities on chest CT; AND

C: Absence of pulmonary infection on initial work-up; Minimum criteria include negative respiratory pathogen panel, influenza PCR or rapid test if local epidemiology supports testing. All

other clinically indicated respiratory ID testing (e.g., urine antigen for Streptococcus pneumonia and Legionella, sputum culture if productive cough, Bronchoalveolar lavage (BAL) culture if done, blood culture, HIV-related opportunistic respiratory infections if appropriate) must be negative; **AND** 

D: No evidence in medical record of alternative plausible diagnoses (e.g., cardiac, rheumatologic or neoplastic process).

## Probable case: A, B and D above; AND

Infection identified via culture or PCR [polymerase chain reaction], but clinical team<sup>(\*\*)</sup> believes this is not the sole cause of the underlying respiratory disease process **OR** Minimum criteria to rule out pulmonary infection not met (testing not performed) and clinical team<sup>(\*\*)</sup> believes this is not the sole cause of the underlying respiratory disease process

\*Using an electronic device (e.g., electronic nicotine delivery system (ENDS), I Quit Ordinary

Smoking (IQOS), electronic cigarette, e-cigarette, vaporizer, vape(s), vape pen, dab pen, or other device) or dabbing to inhale substances (e.g., nicotine, marijuana, THC, THC concentrates, CBD, synthetic cannabinoids, flavorings, or other substances).

\*\*Clinical team caring for the patient

Likewise, the FDA also issued a directive on September 6 to urge hospitals nationwide to provide information.<sup>7)</sup>

According to FDA reports, 127 cases of convulsions caused by electronic cigarettes have also been reported in the United States.<sup>4, 6)</sup>

The FDA continues to monitor 35 reports of convulsions by electronic cigarette users since April this year, and 92 new reports have been received since, for a total of 127 reports. Because FDA relies on a voluntary adverse event reporting system, there may be more unreported cases.

According to the FDA announcement, most electronic cigarette users who had convulsions were adolescents and children, some of whom used electronic cigarettes for the first time, while others had used them used regularly.

The FDA would like to receive the following information when reporting an adverse case.<sup>5</sup>

When reporting an adverse experience, please be sure to include:

- The name of the manufacturer
- The brand name, model, and serial number of the device or e-liquid, if applicable
- Where the device or e-liquid was purchased
- Whether the device or e-liquid was modified in any way or whether there was a device malfunction
- Whether other tobacco products, medications, supplements or other substances were used

- Whether there were any other symptoms (i.e., nausea, vomiting) or warning right before the adverse experience, such as change in the user's behavior, alertness, vision or hearing
- Details about product use preceding the event (duration, amount and intensity of e-cigarette use)
- Details about health effects, including specific areas of the body affected, how symptoms progressed, how long they lasted, the course of the recovery, and the medical testing or care and decisions rendered

While adverse events from heated tobacco and electronic cigarettes are reported in detail from around the world, action by public health authorities in Japan might seem slow.

Thus, I think that we should establish a research team or organization to examine possible cases of pneumonia and convulsions caused by heated cigarettes and electronic cigarettes.

Thank you for your consideration.

 Takahiro Kamada, Yosuke Yamashita, and Hiromi Tomioka : Acute eosinophilic pneumonia following heat-not-burn cigarette smoking. Respirol Case Rep. 2016 Nov; 4(6): e00190. PMCID: PMC5167280 Published online 2016 Oct 3. doi: 10.1002/rcr2.190

2) Aokage T, Tsukahara K, Fukuda Y, Tokioka F, Taniguchi A, Naito H, Nakao A.: <u>Heat-not-burn cigarettes induce fulminant acute eosinophilic pneumonia requiring extracorporeal membrane</u> <u>oxygenation.</u>

Respir Med Case Rep. 2018 Dec 4;26:87-90. doi: 10.1016/j.rmcr.2018.12.002. eCollection 2019.

- 3) Jennifer E. Layden, M.D., Ph.D., Isaac Ghinai, M.B., B.S., Ian Pray, Ph.D., Anne Kimball, M.D., Mark Layer, M.D., Mark Tenforde, M.D., Ph.D., Livia Navon, M.S., Brooke Hoots, Ph.D., Phillip P. Salvatore, Ph.D., Megan Elderbrook, M.P.H., Thomas Haupt, M.S., Je!rey Kanne, M.D., Megan T. Patel, M.P.H., Lori Saatho!-Huber, M.P.H., Brian A. King, Ph.D., M.P.H., Josh G. Schier, M.D., Christina A. Mikosz, M.D., M.P.H., and Jonathan Meiman, M.D.et : Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Preliminary Report | NEJM , 2019/09/11 9'32
- 4) FDA investigating 127 reports of seizures, neurological symptoms related to vaping.

https://edition.cnn.com/2019/08/07/health/ecigarette-seizure-fda-investigation/index.html

5) FDA: Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults.

https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involvin g-youth-and-young-adults

6) FDA investigating 127 reports of seizures after vaping.

https://www.cnbc.com/2019/08/07/fda-investigating-127-reports-of-seizures-after-vaping.html

7) FDA asks hospitals to report injuries, illnesses related to e-cigarette.

https://technology.inquirer.net/90546/fda-asks-hospitals-to-report-injuries-illnesses-related-to-e-cigarette

Conclusion