MEMORANDUM

TO: Medical Officers of Health and Associate Medical Officers of Health

RE: Ontario’s response to the Japanese temporary suspension for use of the HPV vaccines

On June 15, 2013, the Japanese health ministry issued a nationwide notice that HPV vaccines be temporarily not recommended in females pending investigation of 42 reports of serious chronic pain. This action is precautionary and HPV vaccines are still available in Japan for individuals who wish to receive them.

In light of the recent decision by the Japanese health ministry, Health Canada performed a Health Risk Assessment (HRA) to determine whether the reports from Japan change the benefit-risk profile of the HPV vaccines authorized for use in Canada. This HRA is based on adverse events following immunization (AEFI) reported to the Public Health Agency of Canada (PHAC) by provinces and territories and reports from manufacturers required to report AEFIs to Health Canada since 2011.

The results of the Health Canada HRA indicate that based on the information received to date and with over four million doses of HPV vaccines distributed, there is no new safety signal for either of the HPV vaccines (Gardasil® and Cervarix™).

In addition, a recent safety update on HPV vaccines (June 13, 2013) from the World Health Organization’s (WHO) Global Advisory Committee on Vaccine Safety (GACVS) concluded that with more than 170 million doses distributed worldwide, the safety profile of HPV vaccines continues to be reassuring. GACVS acknowledges the recent events in Japan and notes that there is little reason to suspect that the cases of chronic pain being reported from Japan are associated with the HPV vaccine, given its growing use globally in the absence of a similar signal elsewhere.

In November 2012, Public Health Ontario (PHO) released a report on AEFIs in Ontario’s school-based HPV immunization program. Between 2007 and 2011 almost 700 000 doses of Gardasil® (HPV4) were distributed in Ontario. During this same period 133 confirmed AEFIs were reported for an overall reporting rate of 19.2 per 100 000 doses distributed. Frequently reported events included allergic skin reactions, rash and local/injection site reactions. Ten serious AEFIs were reported (7.5% of reports) including 2 anaphylaxis, 2 seizures, 1 thrombocytopenia and 1 death. Further review found that the reports of anaphylaxis did not meet the Brighton anaphylaxis definition and the death was attributed to a pre-existing cardiac condition. One case of chronic musculoskeletal pain was reported in 2011. Overall, these findings are consistent with the safety profile of HPV4 vaccine from pre-licensure clinical trials and post-marketing surveillance reports and importantly, no new safety signals were identified. It is important to note that provincially reported AEFIs are temporally associated and not necessarily causally linked to HPV4 vaccine. HPV4 vaccine AEFI information is based upon iPHIS data only and not comprehensive chart review.
Based on international, national and provincial post-marketing safety surveillance information on HPV4 vaccine, there are no new safety concerns related to the use of Gardasil®. The Ministry of Health and Long-Term Care (the ministry) recommends continued vaccine safety monitoring through timely AEFI investigation and reporting in iPHIS as per the Infectious Diseases Protocol, Appendix B: Provincial Case Definitions for AEFI available from:

Based on an assessment of all available evidence to date, the ministry is not recommending any changes to the current school-based HPV immunization program in Ontario.

As a reminder, a new provincial AEFI reporting form (replacing the previous PHAC form) is available for health care providers to report AEFIs to the public health unit. This form, as well as an AEFI Question and Answer document for providers, is available from:

For questions about AEFI reporting or any vaccine safety concerns, please contact PHO Immunization & Vaccine-Preventable Diseases Team (ivpd@oahpp.ca).

On a final note, I would like to underscore the importance of HPV immunization by sharing the results of a recent study from the US Centers for Disease Control and Prevention (CDC)\(^1\) comparing infection rates in girls before and after the vaccine became available. Among females aged 14 to 19 years, the vaccine-type HPV prevalence decreased from 11.5% in 2003-2006 to 5.1% in 2007-2010, a decline of 56%. The vaccine effectiveness of at least one dose of vaccine was concluded to be high (82%).

I would like to acknowledge and thank you for the important work that is being done related to supporting the HPV immunization program in the public health units across the province.

Original signed by

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Chief Medical Officer of Health

c. Vaccine Preventable Disease Managers

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