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Dear Healthcare Professionals,

Zostavax vaccine: Safety measures to address risk of infection with the vaccine virus

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that it has required new warnings for Zostavax vaccine to address the risk of fatal disseminated vaccine strain varicella zoster virus infection. A new boxed warning has been added to the Product Information (PI) with information about managing this risk, including pre-screening and risk-based assessment prior to use of the vaccine, and management of suspected cases. A corresponding warning has also been added to the Consumer Medicine Information (CMI) for Zostavax.

The sponsor of Zostavax, Seqirus, is also required to implement the following activities:

- Provide a Patient Alert Card to health professionals to give to each patient receiving Zostavax.
- Provide refrigerator stickers to all providers of Zostavax to place on the fridge in which the medicine is stored.
- Send letters to inform health professionals of the content of the boxed warning statement.
- Update the current Risk Management Plan and Periodic Safety Update Reports to include consideration of this risk.

The TGA has been closely monitoring reports of disseminated vaccine strain varicella zoster infection and has published several safety alerts in response to three deaths related to this condition following vaccination with Zostavax. Investigation of this safety concern has found that the benefits of Zostavax continue to outweigh the risks, but additional risk mitigation is required.

Information for health professionals:

The PI for Zostavax has been updated with the following boxed warning:

- Rarely, disseminated varicella zoster virus (VZV) infection with vaccine (Oka) strain can occur in patients following administration of the live-attenuated Zostavax vaccine. There have been

fatal reports of disseminated vaccine-related VZV infection in Australia, including in patients on low dose immunosuppressive medication. The risk increases with the degree of immunosuppression.

- Zostavax is contraindicated in patients with current or recent severe immunocompromising conditions from either a primary or acquired medical condition or medical treatment.
- Careful pre-screening and a risk-based assessment is required prior to administration of any dose of Zostavax. If appropriate, this assessment should include medical specialist consultation and potentially screening for pre-existing antibody to VZV. In such cases, vaccination should be deferred until such advice and/or results have been obtained.
- The Australian Immunisation Handbook contains specific guidance about Zostavax administration in patients who are immunocompromised or have medical conditions that place them at risk of immunocompromise. If uncertain about a person's level of immunocompromise and whether vaccination is safe, do not vaccinate and seek further specialist advice.
- Any patient who experiences a disseminated vesicular (chickenpox-like) rash 2 to 4 weeks after vaccine administration, or who feels unwell or has a fever, should seek medical attention immediately and ensure that their treating health professional is aware of their recent vaccination history.
- If inadvertent vaccination in an immunosuppressed patient has occurred, the patient should be advised regarding the potential for disseminated VZV infection and the need to seek medical advice should symptoms suggestive of this occur, so that they can be considered for pre-emptive antiviral therapy.
- If a recent Zostavax recipient is suspected of having disseminated VZV infection, the healthcare professional should: conduct appropriate diagnostic testing early in consultation with a clinical microbiologist or infectious diseases physician; where appropriate, initiate appropriate empiric antiviral therapy whilst awaiting test results; where feasible, cease immunosuppression in consultation with their treating specialist.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/alert/zostavax-vaccine-2

In Hong Kong, Zostavax For Vaccine (HK-55419) is a pharmaceutical product registered by Merck Sharp & Dohme (Asia) Ltd, and is a prescription-only medicine. So far, the Department of Health (DH) has received 6 cases of adverse events following immunisation with Zostavax, but none of them involved death. Related news was previously issued by TGA, and was posted on the Drug Office website on 8 Mar 2017, 7 Jul 2020 and 23 Dec 2020. The current local product insert includes information on "Do not administer Zostavax to individuals who are immunodeficient or immunosuppressed due to disease or therapy, as serious or fatal disseminated vaccine strain varicella-zoster virus disease may occur." In light of the above TGA's announcement, the matter will be discussed by the Registration Committee of the

Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)