衞生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Tecentriq® (atezolizumab) and new safety concern of immune-related nephritis

Your attention is drawn to the Health Sciences Authority's (HSA) announcement that Roche Singapore Pte Ltd would like to inform healthcare professionals of the new safety concern of immune-related nephritis associated with Tecentriq® (atezolizumab).

Immune-related nephritis is a rare complication of checkpoint inhibitors therapy, with the most commonly reported underlying pathology being acute tubulo-interstitial nephritis. The most common presentation of immune-related nephritis includes asymptomatic increase in creatinine levels. In the absence of alternative etiologies (e.g. prerenal and postrenal causes, concomitant medications), immune-related nephritis is defined as a renal dysfunction requiring steroids treatment and/or confirmed by biopsy.

Healthcare professionals are advised to monitor patients for changes in renal function and to withhold Tecentriq® for moderate (Grade 2) immune-related nephritis, and permanently discontinue Tecentriq® for severe nephritis (Grade 3 and 4). It is also recommended to administer corticosteroids and/or additional immunosuppressive agents as clinically indicated.

Roche Singapore Pte Ltd is working with HSA to update the Singapore package insert for Tecentriq® to include the risk of immune-related nephritis.

Please refer to the following website in HSA for details:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Dear_Healthcare_Professional_Letters/2018/tecentriq-atezolizumabandnewsafetyconcernofimmunerelatednephriti.html

In Hong Kong, Tecentriq Concentrate For Solution For Infusion 1200mg/20ml (HK-65567) is a pharmaceutical product registered by Roche Hong Kong Limited (Roche HK), and is a prescription-only medicine. So far, the Department of Health (DH) has received 15 cases of adverse drug reaction related to atezolizumab, but these cases are not related to immune-related nephritis. Roche HK has recently submitted an application to update the package insert of the product, including the safety information on immune-related nephritis. DH will work with Roche HK to update the product's safety information and will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Please report any adverse events caused by drugs to the Pharmacovigilance 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)