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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

21 Mar 2024

Dear Healthcare Professionals,

Updated warnings of faricimab (Vabysmo): retinal vasculitis risk

Your attention is drawn to the Australia Therapeutic Goods Administration's (TGA) announcement that TGA's investigation into the risk of retinal vasculitis and/or retinal occlusive vasculitis in patients being treated with faricimab (Vabysmo) found that stronger warnings regarding this risk were needed in the Product Information (PI) and Consumer Medicine Information (CMI).

TGA's Pharmacovigilance Branch undertook a signal investigation in Nov 2023 to assess the risk of retinal vasculitis and/or retinal occlusive vasculitis with faricimab. Retinal vasculitis and retinal occlusive vasculitis are serious adverse events that could lead to permanent vision loss and require prompt diagnosis and management.

Sections 4.4 and 4.8 of the Vabysmo PI were updated to reflect the additional safety information and a Dear Health Care Professional letter was sent to ophthalmologists who prescribe intravitreal injections. The CMI was updated to reflect the changes.

Additional warnings added to the Australian PI:

4.4 Special warnings and precautions for use

Retinal Vasculitis and/or Retinal Occlusive Vasculitis: Retinal vasculitis and/or retinal occlusive vasculitis, typically in the presence of intraocular inflammation, have been reported with the use of Vabysmo in the postmarketing setting. Discontinue treatment with Vabysmo in patients who develop these events. Patients should be instructed to report any change in vision without delay (see section 4.8).

4.8 Adverse effects (undesirable effects)

Postmarketing Experience: Rare cases of retinal vasculitis and/or retinal occlusive vasculitis have

been spontaneously reported in the postmarketing setting. Retinal vasculitis and retinal occlusive vasculitis have also been reported in patients treated with intravitreal therapies.

A search of TGA's Adverse Events Management System database on 19 Dec 2023 for 'faricimab' and reaction terms 'vasculitis' and 'retinal vasculitis' returned 3 related adverse event reports.

Health professionals should be alert to the updated warnings and should inform patients and carers of the potential retinal vasculitis and/or retinal occlusive vasculitis risk associated with faricimab use.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/news/safety-updates/updated-warnings-faricimab-vabysmo-retinal-vasculitis-risk

In Hong Kong, there is one registered pharmaceutical product containing faricimab, namely Vabysmo Solution For Intravitreal Injection 6mg/0.05ml (HK-67656). The product is registered by Roche Hong Kong Limited. It is a prescription-only medicine. So far, the Department of Health (DH) has received 5 cases of adverse drug reaction related to faricimab, but these cases were not related to retinal vasculitis or retinal occlusive vasculitis. In light of the above TGA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. 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 Clinical Trials and 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,

(Terence MAN)
for Assistant Director (Drug)