衞生署藥物辦公室
藥物資訊及進出口管制科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.: DH DO DIMC/7-30/1

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

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower
Landmark East, 100 How Ming Street
Kwun Tong, Kowloon, Hong Kong

17 June 2024

Dear Healthcare Professionals,

CAR T-cell medicines: PRAC identifies risk of secondary malignancies of T-cell origin

Your attention is drawn to the European Medicines Agency's (EMA) announcement that its Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that secondary malignancies of T-cell origin (a new cancer, different from the previous one, that begins in a type of white blood cells of the immune system called T-cells) may occur after treatment with chimeric antigen receptor (CAR) T-cell medicines.

The committee evaluated data on 38 cases of secondary malignancy of T-cell origin, including T-cell lymphoma and leukaemia, reported among approximately 42,500 patients who have been treated with CAR T-cell medicines. Tissue samples were tested in half of the cases, revealing the presence of the CAR construct in 7 cases. This suggests that the CAR T-cell medicine was involved in disease development. The secondary malignancies of T-cell origin have been reported within weeks and up to several years following administration of CAR T-cell medicines. Patients treated with these medicines should be monitored life-long for new malignancies.

CAR T-cell medicines belong to a type of personalised cancer immunotherapies where one type of a patient's white blood cells (T-cells) are reprogrammed and reinjected to attack the cancer.

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Six CAR T-cell products are approved in the European Union (EU): Abecma, Breyanzi, Carvykti, Kymriah, Tecartus and Yescarta. These medicines are used to treat blood cancers such as B-cell leukemia, B-cell lymphoma, follicular lymphoma, multiple myeloma and mantle cell lymphoma in patients whose cancer has come back (relapsed) or has stopped responding to previous treatment (refractory).

Since approval, the product information has advised that patients treated with these products may develop secondary malignancies. The product information and the risk management plans will be updated to include the new information concerning secondary malignancy of T-cell origin.

Healthcare professionals will be informed of the PRAC's review conclusion on secondary malignancies of T-cell origin, including chimeric antigen receptor (CAR)-positive malignancies.

Healthcare professionals will be reminded about the need for life-long monitoring of patients for cases of secondary malignancies.

Please refer to the following website in EMA for details:

https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-10-13-june-2024

In Hong Kong, Kymriah (tisagenlecleucel) Dispersion for Infusion (HK-66588) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Limited. It is a prescription-only medicine. So far, with regard to tisagenlecleucel, the Department of Health (DH) has received 18 cases of adverse drug reaction, of which 8 cases were reported as malignancies. The other products mentioned in the above EMA's announcement are not registered pharmaceutical products in Hong Kong.

The current product insert of the locally registered Kymriah product already includes safety information about secondary malignancies.

Related news was previously issued by the United States Food and Drug Administration (US FDA) and the EMA, and was posted on the Drug Office website on 29 Nov 2023, 15 Jan 2024, 24 Jan 2024 and 19 Apr 2024. Letters to inform local healthcare professionals about the risk of T-cell malignancies were issued by the DH on 24 Jan 2024. The matters will further 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)