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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Veklury (remdesivir): Assessing the potential risks of acute kidney injury (AKI) and acute renal failure (ARF)

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risks of acute kidney injury (AKI) and acute renal failure (ARF) with Veklury (remdesivir) to analyse the emerging information and determine if further measures were needed in Canada. This safety review was initiated following the submission of international case reports of AKI/ARF from the manufacturer.

Veklury (remdesivir) is authorized for sale in Canada to treat coronavirus disease 2019 (COVID-19) in adults and adolescents with pneumonia (a lung infection) and requiring oxygen. This authorization includes conditions on the manufacturer to provide additional information to Health Canada on the drug's performance, along with active safety monitoring.

At the time of the review, the Canadian product safety information (Canadian Product Monograph) for Veklury included information on potential kidney toxicity and recommended measuring kidney function before starting Veklury and during treatment. It also advised against using Veklury with drugs that reduce kidney function, or in patients with severe kidney problems. The purpose of this review was to assess if additional actions were required in Canada.

Health Canada reviewed the available information from searches of the Canada Vigilance database, international databases, published literature, and information received from the manufacturer. At the time of the review, Health Canada had not received any Canadian reports of AKI/ARF related to Veklury use. Health Canada reviewed 88 international case reports of AKI/ARF in patients receiving Veklury. 60 of these foreign cases were from the Canada Vigilance database. Of the 88 case reports, 64 cases were found to be possibly linked with the use of Veklury, 14 cases were unlikely to be linked, and 10 cases did not have enough information to be further assessed. In all 64 cases assessed as possibly linked, the role of Veklury in causing AKI/ARF could not be established due to several contributing factors such as, other medications taken by the patients, existing medical conditions and/or COVID-19 illness that may have contributed to AKI/ARF.

Health Canada also looked at additional information available from 10 articles in published scientific literature and 4 studies provided by the manufacturer on the risk of AKI/ARF with Veklury use. Overall, there is limited information suggesting that treatment with Veklury in COVID-19 patients can lead to AKI/ARF.

Based on Health Canada's review of the available information, a direct link between the use of Veklury and the risk of AKI/ARF could not be established. The available information does not suggest a change in the overall safety profile for Veklury. Presently, the Canadian Product Monograph (CPM) for Veklury provides appropriate information on kidney toxicity and recommendations on usage, therefore, no updates are required at this time.

Please refer to the following website in Health Canada for details:
https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00264

In Hong Kong, there is one registered pharmaceutical product containing remdesivir, namely Veklury Powder for Concentrate for Solution for Infusion 100mg (HK-66766). The product is registered by Gilead Sciences Hong Kong Limited, and is a prescription-only medicine. The product is indicated for SARS-CoV-2 Infection and is conditionally approved with very limited safety, efficacy, and quality data for public health emergency to satisfy local unmet medical need and the registration status is subjected to be reviewed by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee.

So far, the Department of Health (DH) has received one case of adverse drug reaction related to remdesivir, and this case is related to hypotension.

Related news on the safety signal of acute kidney injury in patients taking remdesivir was previously issued by EMA, and was posted on the Drug Office website on 3 Oct 2020 and 16 Feb 2021. In light of the above Health Canada'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)