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

15 Jul 2024

Dear Healthcare Professionals,

New recommendations for GLP-1 receptor agonists to minimise risk of aspiration and pneumonia aspiration during general anaesthesia or deep sedation

Your attention is drawn to the European Medicines Agency (EMA)'s announcement that its Pharmacovigilance Risk Assessment Committee (PRAC) recommended new measures to minimise the risk of aspiration and pneumonia aspiration reported in patients taking glucagon-like peptide-1 receptor agonists (GLP-1 RAs) who undergo surgery with general anaesthesia or deep sedation. GLP-1 RAs are medicines used for treatment of type 2 diabetes and obesity.

Aspiration and pneumonia aspiration can be caused by accidentally inhaling food or liquid into an airway instead of swallowing it through the oesophagus (the tube that connects the throat to the stomach). It can also occur when stomach content goes back into the throat. Aspiration and pneumonia aspiration complicate between one in 900 to one in 10,000 general anaesthesia procedures, depending on risk factors.

As part of their action, GLP-1 RAs slow down gastric emptying (emptying of the stomach) and there is a biologically plausible increased risk for aspiration in association with anaesthesia and deep sedation when taking these medicines. Delayed gastric emptying is already listed in the product information for the different GLP-1 RAs: dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide and tirzepatide.

The PRAC reviewed available data including case reports in EudraVigilance, scientific literature and clinical and non-clinical data submitted by the marketing authorisation holders for these medicines.

The committee could not establish a causal association between GLP-1 analogues and aspiration, but because of the known action of delayed gastric emptying and the presence of clinical trial cases and post marketing cases, the PRAC considered that healthcare professionals and patients should be informed on this potential consequence of delayed gastric emptying.

Therefore, the PRAC has recommended that the risk of residual gastric content being present because of delayed gastric emptying should be considered before performing procedures with general anaesthesia or deep sedation. The product information of GLP-1 RAs will be updated accordingly, including a warning to patients that they should inform the doctor involved if they take these medicines and are scheduled to undergo surgery under anaesthesia or deep sedation.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-july-2024

In Hong Kong, there are registered pharmaceutical products containing dulaglutide (4 products), exenatide (1 product), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products), and tirzepatide (6 products). All products are prescription-only medicines. So far, the Department of Health (DH) has received adverse drug reactions with semaglutide (9 cases; of which 3 were related to aspiration pneumonia). The DH has also received adverse drug reactions with dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case) and lixisenatide (1 case), but these cases were not related to aspiration and pneumonia aspiration. The DH has not received any case of adverse drug reaction related to tirzepatide. In light of the above EMA'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)