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Dear Healthcare Professionals,

GLP-1 Receptor Agonists and Dual GLP-1/GIP Receptor Agonists: Strengthened Warnings on Acute Pancreatitis, including Necrotising and Fatal Cases

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that the product information for all Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulintropic polypeptide (GIP) receptor agonists has been further updated to highlight the potential risk of severe acute pancreatitis with these products, including rare reports of necrotising and fatal pancreatitis.

Summary

The product information for all Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulintropic polypeptide (GIP) receptor agonists (dulaglutide, exenatide, liraglutide, semaglutide and tirzepatide) has been further updated to highlight the potential risk of severe acute pancreatitis with these products, including rare reports of necrotising and fatal pancreatitis. Healthcare professionals should remain vigilant for signs and symptoms of acute pancreatitis in patients treated with GLP-1 and GLP-1/GIP receptor agonists.

Advice for Healthcare Professionals:

- be alert to the risk of acute pancreatitis in patients receiving Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/ glucose-dependent insulintropic polypeptide (GIP) receptor agonists. There have been rare reports of necrotising and fatal pancreatitis associated with GLP-1 and GLP-1/GIP receptor agonists
- advise patients to seek urgent medical attention if they develop severe and persistent abdominal pain that may radiate to the back and may be accompanied by nausea and vomiting
- privately prescribed GLP-1s and GLP-1/GIPs may not appear on the patient's medical history so if a patient presents with these symptoms, enquire about GLP-1 or GLP-1/GIP use
- if pancreatitis is suspected, discontinue treatment with the GLP-1 or GLP-1/GIP receptor agonist immediately

- do not restart therapy if the diagnosis of pancreatitis is confirmed
- GLP-1 and GLP-1/GIP receptor agonists should be used with caution in patients with a history of pancreatitis

Advice for Healthcare Professionals to Provide to Patients:

- pancreatitis (inflammation of the pancreas) is a possible side effect with GLP-1 receptor agonists and dual GLP-1/ GIP receptor agonists. In rare reports this can have serious or fatal outcomes
- seek urgent medical attention if you experience severe, persistent abdominal pain, that may radiate to your back and may be accompanied by nausea and vomiting, as this may be a sign of pancreatitis
- do not restart GLP-1 receptor agonist or GLP-1/GIP receptor agonist treatment if pancreatitis is confirmed

Background

Glucagon-like peptide-1 (GLP-1) receptor agonists and dual GLP-1/ glucose-dependent insulintropic polypeptide (GIP) receptor agonists are used for the treatment of type 2 diabetes mellitus and, for some products, for weight management and cardiovascular risk reduction. The GLP-1 and GLP-1/GIP receptor agonists authorised in the UK include dulaglutide, exenatide, liraglutide, semaglutide and tirzepatide. Exenatide is no longer marketed in the UK and lixisenatide is no longer authorised.

Acute pancreatitis is a recognised side effect with GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists. Although the overall frequency remains uncommon, post-marketing experience has shown that some rare reports of acute pancreatitis have been particularly severe, including necrotising and fatal pancreatitis.

In the UK between 2007 and October 2025, the MHRA has received 1,296 Yellow Card reports of pancreatitis (including acute, autoimmune, chronic, haemorrhagic, necrotising, subacute and obstructive forms of pancreatitis) associated with GLP-1 receptor agonists or dual GLP-1/GIP receptor agonists. Of these, 19 reports were fatal and 24 were reported as necrotising pancreatitis. For context, in the past 5 years, it is estimated that roughly 25.4 million packs of the GLP-1 receptor agonists have been dispensed.

The Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM), has advised that the product information for all GLP-1 and dual GLP-1/GIP receptor agonists should be strengthened to highlight the potential severity of acute pancreatitis and to ensure consistency across the class of medicines.

Pancreatitis may be challenging to recognise in its early stages, as initial symptoms such as abdominal pain, nausea or vomiting may be attributed to other causes such as common gastrointestinal side effects

of GLP-1 and GLP-1/GIP treatment or infection. Clinicians should remain vigilant for the possibility of pancreatitis in patients treated with GLP-1 or GLP-1/GIP receptor agonists and investigate in line with local clinical practice. Advise patients to seek urgent medical attention if they develop severe, persistent abdominal pain that may radiate to the back and may be accompanied by nausea and vomiting.

Product Information Update

The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for all UK-authorized GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists have been updated to highlight reports of necrotising pancreatitis and reports with a fatal outcome and to advise that patients seek immediate medical attention if symptoms of acute pancreatitis occur.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/glp-1-receptor-agonists-and-dual-glp-1-slash-gip-receptor-agonists-strengthened-warnings-on-acute-pancreatitis-including-necrotising-and-fatal-cases>

In Hong Kong, there are registered pharmaceutical products containing GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists including 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 has received adverse drug reaction reports with regard to exenatide (2 cases including 1 case related to pancreatitis) and lixisenatide (1 case and is related to pancreatitis); and for dulaglutide (5 cases), liraglutide (1 case), semaglutide (10 cases) with all cases not related to pancreatitis, while no adverse drug reaction report with regard to tirzepatide was received.

Related news on the risk of acute pancreatitis associated with GLP-1 receptor agonists was previously issued by the US Food and Drug Administration and European Medicines Agency, and was posted on the Drug Office website on 15 Mar 2013, 27 Mar 2013 and 27 July 2013. In light of the above MHRA's announcement on highlighting the risk of severe acute pancreatitis including rare reports of necrotising and fatal pancreatitis, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

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,



(Clive CHAN)

for Assistant Director (Drug)