Safety Communication

Risk of Acute Pancreatitis, Including Necrotizing and Fatal Cases, Associated with GLP-1 Receptor Agonists and Dual GLP-1/GIP Receptor Agonists.

Botswana Medicines Regulatory Authority (BoMRA) is responsible for ensuring the safety, efficacy, and quality of medicines and related substances, including human and veterinary medicines, medical devices, and cosmetics in Botswana.

In line with its ongoing surveillance of medicine safety, BoMRA wishes to draw attention to an important emerging safety concern regarding a potential risk of severe complications of acute pancreatitis associated with glucagon-like peptide-1 (GLP-1) receptor agonists and dual GLP-1/(GIP) glucose dependent insilinotropic peptide receptor agonists that has been identified by the Medicines and Healthcare products Regulatory Authority (MHRA).

Background

GLP-1 receptor agonists are authorized for the management of type 2 diabetes mellitus (T2). In some countries, their use is extended to cardiovascular risk reduction in individuals with established cardiovascular disease (CVD) and for chronic weight management. These medicines are commonly administered as subcutaneous injections, although oral formulations are also available.

GLP-1 receptor agonists have been associated with an uncommon risk of acute pancreatitis. Post-marketing surveillance has additionally identified rare cases of severe pancreatitis, including necrotizing and fatal pancreatitis. While no adverse events related to GLP-1 receptor agonists have been reported to BoMRA to date, the increasing use of medically assisted weight loss therapies highlights the importance of raising awareness among healthcare professionals and patients regarding this potential risk. Early recognition of symptoms suggestive of pancreatitis and prompt medical evaluation may facilitate timely intervention and reduce the risk of serious complications.

Acute pancreatitis is a sudden inflammatory condition of the pancreas that may range from a mild to a severe, life-threatening condition. Necrotizing pancreatitis is a severe form of acute pancreatitis characterized by death of the pancreatic tissue. Early symptoms may overlap with common gastrointestinal adverse effects associated with GLP-1 medicines, thereby delaying recognition.

Signs and Symptoms of Acute Pancreatitis

- Abdominal pain-usually sudden in onset and gradually becoming more severe until reaching a constant ache, most often located in the upper abdomen and may radiate directly through to the neck.
- Nausea and Vomiting
- Diarrhea
- Fever, Tachycardia (Fast Heartbeat), hypotension (May present as feeling dizzy, lightheaded or unsteady)
- Bloated
- Feeling weak

Examples of GLP-1 and GLP-1/GIP Receptor Agonists

- Semaglutide (e.g Ozempic, Wegovy)
- Dulaglutide (e.g Trulicity)
- Liraglutide (e.g Victoza)
- Exenatide (e.g Byetta, Bydureon)
- Tirzepatide (e.g Mounjaro)

Some of these products are not currently registered by BoMRA. However, certain products may be available in the country through exemptions.

Advice for Healthcare Professionals

- Discuss the risk of pancreatitis with patients before initiating treatment with GLP-1 receptor agonists or GLP-1/GIP receptor agonists and educate them on early signs to look out for.
- Advise patients to seek urgent medical attention if they develop severe and persistent abdominal pain, which may radiate to the back and may be accompanied by nausea and vomiting.
- Monitor patients receiving these medicines for the early detection of signs and symptoms of acute pancreatitis.
- Discontinue treatment immediately if pancreatitis is suspected.
- Do not restart treatment if pancreatitis is confirmed.
- Assess individual patient risk factors, including a history of pancreatitis, gallstone disease, hypertriglyceridemia, and heavy alcohol use, and consider alternative therapies where appropriate.

Advice for Patients and the Public

- Seek immediate medical attention if you experience severe and persistent stomach pain, especially if the pain spreads to the back or is accompanied by nausea and vomiting.
- Inform your healthcare provider about any history of pancreatitis, gallstones, or excessive alcohol use before starting treatment.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to report all suspected adverse drug reactions associated with these medicines to BoMRA. Reports should include as much information as possible, including medical history, concomitant medications, time to onset, and treatment dates.

Reports may be submitted to the Pharmacovigilance Unit through the available BoMRA reporting channels.

- **ADR Reporting Froms** available in your health facility. You may download the forms from BoMRA website www.bomra.co.bw and email the completed form to **reportadr@bomra.co.bw**
- **eReporting** (who-umc.org) link on the BoMRA website
- **BRIMS:** https://brims.bomra.co.bw
- **Mobile App:** Download “MedSafety App” on Apple store or Google Play Store
- **Through telephone**- 373 1771

For More Information, see references below:

References

- MHRA Drug Safety Update volume 19, issue 6: January 2026: 3. GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists: strengthened warnings on acute pancreatitis, including necrotising and fatal cases - GOV.UK
- https://products.mhra.gov.uk/search/?search=semiglutide&page=1