



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency investigates findings on pancreatic risks with GLP-1-based therapies for type 2 diabetes

The European Medicines Agency is investigating findings by a group of independent academic researchers that suggest an increased risk of pancreatitis (inflammation of the pancreas) and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with so-called GLP-1-based therapies (glucagon-like peptide 1 (GLP-1) agonists and dipeptidylpeptidase-4 (DPP-4) inhibitors).

The findings are based on examination of a small number of pancreatic tissue samples obtained from organ donors with and without diabetes mellitus, who died due to causes other than diabetes. The Agency's Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) are currently investigating the information provided by the researchers to determine the need for possible further regulatory action.

The Agency has not reached any conclusions on this investigation. There is currently no change to the recommendations on the use of these medicines and no need for patients to stop taking their medicines. Healthcare professionals should continue to prescribe these medicines in accordance with the product information.

Effects on the pancreas were identified as a possible risk for these medicines during their initial evaluation for marketing authorisation due to their mechanism of action, and rare cases of pancreatitis have been reported. Warnings for patients and healthcare professionals are included in the product information for all these medicines. In addition, the risk management plans for these medicines instruct the marketing-authorisation holders to closely monitor for adverse effects on the pancreas.

There are also efforts underway to collect safety data on diabetes medicines from independent pharmacovigilance centres across the European Union. The SAFEGUARD study, a study that is funded by the European Commission and carried out within the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), is investigating, among others, evidence for drug-induced pancreatitis for GLP-1-based agents that were authorised before 2011, when the study started.



GLP-1-based therapies are also known as incretin mimetics. In the EU they include exenatide (Byetta, Bydureon), liraglutide (Victoza), lixisenatide (Lyxumia), sitagliptin (Efficib, Januvia, Janumet, Ristaben, Ristfor, Tesavel, Velmetia, Xelevia), saxagliptin (Komboglyze, Onglyza), linagliptin (Jentadueto, Trajenta) and vildagliptin (Eucreas, Galvus, Icandra, Jalra, Xiliarx, Zomarist). These medicines act like hormones called incretins (hormones produced in the intestine) by increasing the amount of insulin released by the pancreas in response to food. They are authorised for use together with diet and exercise in patients with type 2 diabetes.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The article was published online on 22 March 2013 by Diabetes, a journal of the American Diabetes Association (ADA): <http://diabetes.diabetesjournals.org/content/early/2013/03/17/db12-1686.abstract>.
3. The review is carried out under Article 5(3) of Regulation (EC) 726/2004.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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