### Industry **DIGEST**

#### **Industry update**

With so many ongoing advances in the management of diabetes, this section keeps you up to date with product-related developments and other relevant news

# EMA makes recommendations to minimise risk of DKA in people receiving SGLT2 inhibitors

The European Medicines Agency (EMA) has confirmed recommendations to minimise the risk of diabetic ketoacidosis (DKA) in people using sodium—glucose cotransporter 2 (SGLT2) inhibitors.

The advice lists the symptoms of DKA and points out that the condition can occur even in people who are euglycaemic. If DKA is suspected or confirmed, treatment should be stopped immediately and should not be restarted unless another cause is identified and resolved.

The EMA also reminds practitioners that SGLT2 inhibitors are not authorised for treating type 1 diabetes, noting that some cases of DKA have occurred with off-label use.

#### NICE guideline on type 2 diabetes management

After consultation of two draft versions, NICE published the final version of the updated type 2 diabetes management guidelines in December 2015.

The guideline was originally scheduled for release in June 2015 but was delayed after criticism by stakeholder organisations. The updated version is more widely supported and brings the recommendations more in line with other international guidance. It also includes an algorithm which incorporates all the available medicine classes to people with type 2 diabetes.

A detailed review of the changes can be found in our sister journal, *Diabetes & Primary Care*, volume 18, issue 1.

### **Top-line data show cardiovascular benefit with liraglutide**

Novo Nordisk have announced top-line results from the LEADER (Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results – A Long Term Evaluation) trial, demonstrating that, in combination with standard care, liraglutide is superior to placebo in terms of a composite endpoint of cardiovascular death, non-fatal myocardial infarction (MI) and non-fatal stroke.

Liraglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, is now the second of the new antidiabetes drugs to demonstrate cardiovascular benefit,

following positive results with the sodium—glucose cotransporter 2 inhibitor empagliflozin. In contrast to the latter, however, liraglutide was effective in preventing the individual outcomes of nonfatal MI and non-fatal stroke, not just the combined endpoint.

Top-line data like these are usually released early once the outcome of a trial is known, in order to satisfy US financial regulations. The full trial data will be published in June at the American Diabetes Association's Annual Scientific Sessions in New Orleans.

## SMC approves two GLP-1 analogues for use in Scotland

The Scottish Medicines Consortium (SMC) has announced that dulaglutide and albiglutide, two once-weekly glucagon-like peptide-1 (GLP-1) receptor agonists, have been approved for use as add-on therapy in Scotland.

Dulaglutide 1.5 mg (Trulicity®; Eli Lilly and Company) is approved as part of triple therapy in people with inadequate glycaemic control on two oral anti-diabetes drugs, as an alternative GLP-1 receptor agonist option. The SMC has not reviewed the agent for its other indication – as monotherapy in people for whom metformin is contraindicated – and currently does not recommend it for this use.

Albiglutide (Eperzan®; GlaxoSmithKline) is approved as an alternative onceweekly GLP-1 receptor agonist for use in combination with oral anti-diabetes agents as a third-line pre-insulin treatment option. The SMC has not reviewed and does not recommend its use as monotherapy.

# FreeStyle<sup>®</sup> Libre receives CE mark for use in children

Abbott have announced that its FreeStyle<sup>®</sup> Libre flash glucose monitoring system has received the CE (Conformité Européenne) mark for use in children and teens aged 4–17 years with diabetes. The device can now be marketed for this age group.

The FreeStyle Libre system eliminates the need for routine finger pricks and allows children and their parents to test blood glucose levels simply by passing the device over a sensor that can be worn on the back of the upper arm for up to 14 days.

