MHRA approves GLP-1 receptor agonist for new indication

First weight-loss drug approved in the UK as a preventative treatment for those with established cardiovascular disease.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has approved a new indication for semaglutide (Wegovy) to reduce the risk of overweight and obese adults suffering serious heart problems or strokes. The GLP-1 receptor agonist is already approved for use, alongside diet, physical activity and behavioural support, in the treatment of obesity and for weight management.

Semaglutide becomes the first weight-loss drug to be approved to prevent major adverse cardiovascular events (MACE), such as death from cardiovascular causes, non-fatal heart attack and non-fatal stroke, in people with established cardiovascular disease and a BMI ≥27 kg/m^2. The approval follows the publication of trial data showing that once-weekly semaglutide (at a dose of 2.4 mg by subcutaneous injection) lowers the incidence of MACE compared to placebo in this population.

The SELECT trial randomly assigned 17 604 participants to receive either semaglutide or placebo, with a mean exposure of 34.2 months. Semaglutide significantly reduced the risk of MACE by 20%, which occurred in 6.5% of those who received it compared to 8% who received placebo.

Semaglutide represents an important treatment option for the prevention of heart disease and stroke in this high-risk population. The MHRA stresses that healthcare professionals need to support patients to maintain improvements seen with it long into the future. ■