Press release

MHRA approves GLP –1 receptor agonist semaglutide to reduce risk of serious heart problems in obese or overweight adults

Semaglutide is the first weight loss drug approved in the UK as a preventative treatment for those with established cardiovascular disease

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The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 23 July 2024, approved a new indication for semaglutide (Wegovy) to reduce the risk of overweight and obese adults suffering serious heart problems or strokes.

This medicine, a GLP-1 receptor agonist, was already approved for use in the treatment of obesity and for weight management, to be used alongside diet, physical activity and behavioural support.

The approval means that semaglutide is the first weight loss drug to be prescribed to prevent cardiovascular events, such as cardiovascular death, non-fatal heart attack and non-fatal stroke, in people with established cardiovascular disease and a Body Mass Index (BMI) higher or equal to 27 kg/m2.

Cardiovascular disease (https://www.nhs.uk/conditions/cardiovascular-disease/) (CVD) is a general term for conditions affecting the heart or blood vessels. It is usually associated with a build-up of fatty deposits inside the arteries (atherosclerosis (https://www.nhs.uk/conditions/atherosclerosis/)) and an increased risk of blood clots (https://www.nhs.uk/conditions/blood-clots/).

CVD is one of the main causes of death and disability in the UK, but it can often be prevented by leading a healthy lifestyle.

The approval is based on new data from a post-approval clinical study which demonstrated that semaglutide (2.4 mg once weekly by subcutaneous injection, for up to five years) lowers the incidence of major adverse cardiovascular events (MACE) vs placebo.

In a multi-national, multi-centre, placebo-controlled double-blind trial (https://www.nejm.org/doi/full/10.1056/NEJMoa2307563) that randomly assigned over 17,600 participants to receive either Wegovy or a placebo, Wegovy significantly reduced the risk of major adverse cardiovascular events by 20%, such as cardiovascular death,

heart attack and stroke, which occurred in 6.5% of participants who received Wegovy compared to 8% of participants who received placebo.

Shirley Hopper, MHRA Deputy Director of Innovative Medicines, said:

“ Our key priority is enabling access to high quality, safe and effective medical products.

“ We’re assured that the appropriate regulatory standards of safety, quality and effectiveness for the approval of this medicine have been met. This treatment option that prevents heart disease and strokes is an important step forward in tackling the serious health consequences of obesity.

“ As with all medicines, we will keep its safety under close review.”

Professor Bryan Williams, Chief Scientific and Medical Officer at the British Heart Foundation, said:

“ Nearly two thirds of adults in England are living with excess weight or obesity. Those that also have an established cardiovascular disease live with a very high risk that a serious event like a heart attack or stroke could happen.

“ Several recent studies have shown us that semaglutide is an effective tool that can improve the quality of life for those with cardiovascular disease, including by lowering the risk of serious cardiac events.

“ It is important that people using the drug to lose weight and improve their health are given the support they need from healthcare professionals to maintain these improvements long into the future. This means appropriate training and healthcare workforce development, along with policies to create a wider environment that supports everyone to stay as healthy as possible.

Altogether, this can help save lives from the devastating impact of heart attacks and strokes."

The treatment is taken as a solution for injection in a pre-filled pen.

The active ingredient, semaglutide, is a GLP-1 receptor agonist. This mimics the action of the GLP-1 hormone, which is involved in regulating blood sugar levels. Semaglutide binds to GLP-1 receptors on pancreatic cells, enhancing the insulin secretion in response to meals, reducing glucagon release and slowing the gastric emptying process. This helps to promote weight loss.

The most common side effects of the medicine are gastrointestinal disorders including nausea, diarrhoea, constipation and vomiting.

As with any medicine, the MHRA keeps the safety and effectiveness of semaglutide under close review. Anyone who suspects they are having a side effect from this medicine is encouraged to talk to their doctor, pharmacist or nurse and report it directly to the Yellow Card scheme, either through the website (https://yellowcard.mhra.gov.uk/) or by searching the Google Play or Apple App stores for MHRA Yellow Card.

Notes to editors

1. Authorisation for this new indication for semaglutide (Wegovy) was granted on 23 July 2024 to Novo Nordisk.
2. The authorisation was granted as part of the International Recognition Procedure (IRP), via the reference regulator, the Food and Drug Administration in the USA. Launched in January this year, the IRP allows the MHRA to accelerate the assessment of new medicines by taking into account the expertise and decision-making of trusted regulatory partners in the authorisation process.
3. More information can be found in the Summary of Product Characteristics and Patient

Information leaflets which will be published on the MHRA Products website (https://products.mhra.gov.uk/) within 7 days of approval.

4. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
5. The MHRA is an executive agency of the Department of Health and Social Care.
6. For media enquiries, please contact the news centre on 020 3080 7651 or newscentre@mhra.gov.uk

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