EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2021
EMA/CHMP/639299/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Wegovy

semaglutide

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Wegovy, intended for the treatment of people with obesity or who are overweight in the presence of other related conditions.

The applicant for this medicinal product is Novo Nordisk A/S.

Wegovy will be available as 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg solutions for injection. The active substance of Wegovy is semaglutide, a glucagon-like peptide-1 (GLP-1) analogue (ATC code: A10BJ06). The mechanism by which semaglutide treatment results in weight loss is not entirely understood, but among other functions, GLP-1 appears to regulate appetite by increasing feelings of satiety and fullness while lowering feelings of hunger and reducing energy intake.

The benefit of Wegovy is its clinically relevant effect on weight loss when used in combination with a reduced-calorie diet and increased physical activity for weight management in people with obesity or who are overweight in the presence of other related conditions. The most common side effects are gastrointestinal side effects, including nausea, diarrhoea, constipation and vomiting.

The full indication is:

> Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of
>
> - ≥30 kg/m^2 (obesity), or
> - ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.