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FDA Approves FluMist Nasal Spray for Self- or Caregiver-Administration

Date: September 20, 2024

On September 20, 2024, the U.S. Food and Drug Administration (FDA) approved FluMist, a nasal spray influenza vaccine, for self- or caregiver-administration, marking a significant milestone in flu prevention. This is the first flu vaccine that does not require administration by a healthcare provider, offering increased convenience, flexibility, and accessibility for individuals and families. FluMist is approved for the prevention of influenza caused by virus subtypes A and B in individuals aged 2 to 49 years.

Influenza is a common and contagious respiratory disease that typically circulates during the fall and winter in the U.S. The disease can cause a range of symptoms, including but not limited to fever, coughing, sore throat, and runny nose. Annual vaccination is the best way to prevent influenza and the serious complications the disease may lead to.

FluMist contains a weakened form of live influenza virus strains and is sprayed into the nose. It has been in use since 2003, initially approved for individuals aged 5 to 49 years, with its approval expanded in 2007 to include children as young as 2 years old. A prescription is still required, and caregivers aged 18 years or older must administer the vaccine to children aged 2 to 17 years, as self-administration is not permitted for this age group.

FluMist is available through third-party online pharmacies, where individuals can complete a screening and eligibility assessment. Eligible recipients will receive the vaccine along with detailed instructions for storage, administration, and disposal. The most commonly reported side effects include fever in young children, runny nose, nasal congestion, and sore throat in adults.

Influenza remains a significant public health concern, causing millions of illnesses, thousands of hospitalizations, and deaths annually in the U.S. The FDA's approval of FluMist for self- or caregiver-administration reflects its ongoing commitment to improving public health by increasing access to safe and effective vaccines.

Source: www.fda.gov

Tirzepatide Demonstrates Potential Clinical Benefits in Adults with Obstructive Sleep Apnea and Obesity

Date: October 3, 2024

Obstructive sleep apnea is caused by repetitive pharyngeal collapse during sleep, which eventually results in consequent hypoxemia and hypercapnia. Currently, there is no medication being approved for treating obstructive sleep apnea and positive airway pressure therapy remains as the mainstay for symptomatic relief associated with obstructive sleep apnea.

As excess adiposity is considered as the major risk factor for obstructive sleep apnea, substantial weight reduction has been recognized as one of the recommended treatments in various clinical guidelines. Tirzepatide, a long-acting glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist, has previously demonstrated its significant effect in weight reduction.

The SURMOUNT-OSA trials were two phase 3, double-blind, randomized studies to evaluate the efficacy and safety of tirzepatide in obese adults with moderate-to-severe obstructive sleep apnea. Eligible participants were assigned in 1:1 ratio in both studies, where the treatment group received once weekly subcutaneous tirzepatide (n=234) or placebo (n=235) injection for 52 weeks. The study endpoint included the change in apnea-hypopnea index (AHI) and body weight from baseline, as well as sleep-related patient-reported outcomes.

A significant estimated treatment difference of -20.0 events per hour in terms of AHI was recorded when comparing the tirzepatide and placebo at week 52 (95% confidence interval [CI], -25.8 - -14.2; P<0.001). Adults who received weekly tirzepatide were also found to have a greater percentage decrease in body weight (estimated treatment difference = -16.1%; 95% confidence interval [CI], -18.0% - -14.2%; P<0.001). Mild-to-moderate gastrointestinal-related events were the mostly frequently reported adverse events.

In summary, tirzepatide has showcased its potential benefits in obese adults with obstructive sleep apnea with clinical improvements on sleep-disordered breathing and sleep-related impairments.

Source: www.nejm.org

Finerenone Reduces Worsening Heart Failure Events in Heart Failure Patients with Mildly Reduced or Preserved Ejection Fraction

Date: October 24, 2024

Heart failure with preserved ejection fraction (HFpEF) is clinically characterized as heart failure where the left ventricular ejection fraction exceeds 50%. Currently approved treatment choice for HFpEF management is limited to sodium-glucose co-transporter 2 inhibitors (SGLT2i) which remains an unmet need in this population. Finerenone is a nonsteroidal mineralocorticoid receptor antagonist that has been proven effective in reducing risk of cardiovascular events in patients with chronic kidney disease and type 2 diabetes, and its efficacy and safety among heart failure patients with mildly reduced (HFmrEF) or preserved ejection fraction remains uncertain.

In this international, parallel-group, double-blind and randomized trial, eligible patients were randomly assigned in a 1:1 ratio to receive once daily finerenone (n=3003) or matching placebo (n=2998) in addition to their ongoing usual therapy. Maximum dosing of finerenone in the treatment was 20mg or 40mg daily, depending on the baseline estimated glomerular filtration rate (eGFR). The primary outcome was a composite of total worsening heart failure events and death from cardiovascular causes. Clinical safety of finerenone usage in HFmrEF and HFpEF patients was also evaluated.

The total number of worsening heart failure events was significantly lower in the finerenone group in comparison with the placebo group (rate ratio = 0.82; 95% confidence interval [CI], 0.71 – 0.94; P=0.006) in HFmrEF and HFpEF patients over a median follow-up of 32 months. A sensitivity analysis regarding a composite of the first worsening heart failure event or death from cardiovascular cases also suggested a lower risk in the treatment group (hazard ratio = 0.84; 95% confidence interval [CI], 0.76 – 0.94). Prevalence of serious adverse events were similar in both groups, yet finerenone was found to have a higher risk of developing hyperkalemia during the trial.

In conclusion, finerenone resulted in a significantly lower rate of worsening heart failure events and any associated cardiovascular deaths in HFmrEF and HFpEF patients.

Source: www.nejm.org

Extension of "1+" Mechanism to All New Drugs Comes Effective on November 1, 2024

Date: October 25, 2024

As specified by the Pharmacy and Poisons Ordinance (Cap. 138), any kinds of pharmaceutical products must satisfy the criteria of safety, efficacy and quality and be registered before they can be sold or supplied locally. The "1+" mechanism launched since November 1, 2023 allowed new drugs indicated for the treatment of life-threatening or severely debilitating diseases that are supported by local clinical data to submit approval from one reference drug regulatory authority for applications for new drug registration.

On October 25, 2024, the Department of Health has announced the arrangement for expanding the "1+" mechanism to all new drugs, including vaccines and advance therapy products, based on the new measures in "The Chief Executive's 2024 Policy Address". Relevant consultation services will also be introduced for new drug applications under the "1+" mechanism in the first quarter of 2025 to facilitate the entire application progress.

The extension of "1+" mechanism comes into effect starting from November 1, 2024. It is expected to attract more new drugs seeking approval for local registration and thus giving patients more choices and further strengthening the local capacity for drug evaluation.

Source: www.drugoffice.gov.hk

Once-Weekly Semaglutide in Persons with Obesity and Knee Osteoarthritis

Date: October 30, 2024

Obesity is a known risk factor for knee osteoarthritis, exacerbating pain, inflammation, and joint deterioration. While weight loss is a critical management strategy, achieving sustainable weight reduction remains challenging. There is an unmet need for weight-management medications in individuals with obesity-related knee osteoarthritis. The effects of glucagon-like peptide-1 (GLP-1) receptor agonists in this population are not well established.

This 68-week randomized, double-blind, placebo-controlled trial, conducted at 61 sites across 11 countries, evaluated the efficacy and safety of semaglutide (2.4 mg) in individuals with a BMI ≥30 and diagnosed knee osteoarthritis. Participants were randomly assigned in a 2:1 ratio to receive semaglutide or a placebo once weekly, alongside lifestyle interventions such as dietary adjustments. The primary end points were the percentage change in body weight and the change in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score from baseline to week 68. The secondary end point was the physical-function score on the 36-Item Short Form Health Survey (SF-36).

A total of 407 participants were enrolled (271 in the semaglutide group, 136 in the placebo group). The mean change in body weight from baseline to week 68 was −13.7% with semaglutide and −3.2% with placebo (estimated difference, −10.5 percentage points; 95% confidence interval [CI], −12.3 to −8.6; P<0.001). WOMAC pain scores improved by −41.7 points with semaglutide versus −27.5 points with placebo (estimated difference, −14.1 points; 95% CI, −20.0 to −8.3; P<0.001). SF-36 physical-function scores also improved more with semaglutide (mean change, 12.0 points vs. 6.5 points; estimated difference, 5.5 points; 95% CI, 3.1 to 8.0; P<0.001). Serious adverse events occurred in 10.0% of the semaglutide group versus 8.1% of the placebo group; gastrointestinal events were the most common side effect.

In conclusion, the study highlights semaglutide as a promising treatment option for patients with obesity and knee osteoarthritis, offering dual benefits of significant weight loss and improved joint health.

Source: www.nejm.org

FDA Proposes Removing Oral Phenylephrine as OTC Nasal Decongestant

Date: November 07, 2024

The U.S. Food and Drug Administration (FDA) has proposed removing oral phenylephrine as an approved active ingredient in over-the-counter (OTC) nasal decongestants. This decision follows a comprehensive review of current and historical data, which concluded that oral phenylephrine is not effective for relieving nasal congestion at the recommended OTC dosage. The proposal does not stem from safety concerns but from lack of efficacy.

Oral phenylephrine is widely used in many OTC cold, cough, and allergy medications, either as a single active ingredient or combined with others, such as acetaminophen or dextromethorphan. The FDA's action does not affect these additional active ingredients or phenylephrine used in nasal sprays, which remain unaffected by this proposal.

The FDA's review incorporated findings from a Nonprescription Drug Advisory Committee meeting in 2023, where experts unanimously agreed that the available scientific evidence does not support oral phenylephrine's effectiveness as a nasal decongestant. This re-evaluation challenges conclusions made 30 years ago based on older data.

Consumers are advised to read Drug Facts labels to identify ingredients in medications. The FDA emphasized that many safe and effective treatment options for nasal congestion, such as nasal sprays or alternative medications, remain available. Consumers can consult healthcare providers for advice on managing symptoms.

The FDA has opened a public comment period on this proposed order. If finalized, products containing oral phenylephrine as a nasal decongestant will need to be reformulated or removed from the market. Manufacturers will be given appropriate time to comply.

This action underscores the FDA's commitment to ensuring OTC drugs meet modern standards of safety and efficacy, protecting public health through rigorous scientific evaluation.

Source: www.fda.gov

CE Questions Answer for 312(D&T)

Review of Vaccines against Herpes Zoster: the Efficacy, Safety and Impact on Quality of Life of Shingrix® and Zostavax®

1. C 2. C 3. D 4. C 5. B 6. D 7. D 8. D 9. A 10. A