The European Medicines Agency’s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has concluded its review of the known risk of pneumonia associated with inhaled corticosteroid (ICS) medicines when used to treat COPD.

The PRAC review confirmed that COPD patients treated with ICS medicines are at increased risk of pneumonia; however the Committee’s view was that the benefits of ICS continue to outweigh their risks. The PRAC also considered whether there were any differences in the risk of pneumonia between these products and did not find conclusive evidence of such a difference. Pneumonia remains a common side effect for all ICS medicines.

Advice for Healthcare Professionals

- Healthcare Professionals should remain vigilant for the possible development of pneumonia in patients treated with ICS for COPD as the clinical features of such infections may overlap with the symptoms of COPD exacerbations.
- Risk factors for pneumonia in patients with COPD include current smoking, age, low BMI and severe COPD.
- The product information (SmPC and PL) for ICS medicines will be updated shortly to reflect the outcome of this review.
- Any suspected adverse reactions should be reported to the HPRA using the usual methods (www.hpra.ie).

Key Message

- The EU review confirmed the known risk that COPD patients treated with inhaled corticosteroids (ICS) medicines are at increased risk of pneumonia.
- This increased risk should be considered a class effect with ICS medicines.
- Healthcare Professionals should be alert to the signs and symptoms of pneumonia, as clinical features may overlap with the symptoms of COPD exacerbations.

*Further details on ICS medicines are available on www.hpra.ie and www.ema.europa.eu

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