



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 May 2015
EMA/285361/2015

Start of review of inhaled corticosteroids for chronic obstructive pulmonary disease

Known risk of pneumonia to be examined in detail

The European Medicines Agency (EMA) has started a review of inhaled corticosteroid-containing medicines used to treat chronic obstructive pulmonary disease (COPD). COPD is a long-term inflammatory disease of the lungs in which the airways and air sacs in the lungs become damaged or blocked. Corticosteroids are widely used in the European Union (EU) to treat COPD and are usually taken by inhalation using an inhaler device.

The review of inhaled corticosteroid-containing medicines has been requested by the European Commission to evaluate the risk of pneumonia (inflammation of the lungs) when these medicines are used for COPD. The risk of pneumonia with these medicines is known and was first identified in 2007 when a study showed that patients treated with an inhaled corticosteroid, fluticasone, were at higher risk of developing pneumonia than those given placebo (dummy treatment).¹ Since then, new studies of individual inhaled corticosteroids and combined study results (meta-analyses) on the class of inhaled corticosteroids have provided further data on the risk of pneumonia and it was considered necessary that a thorough review be performed to further characterise this risk.

EMA will now review all available data on the risk of pneumonia with inhaled corticosteroids for COPD and consider the need to update the existing prescribing advice across the EU.

More about the medicines

Corticosteroids, also known as steroids, are anti-inflammatory medicines used for a wide range of conditions. They are similar to natural hormones normally produced by the adrenal glands (two small glands located above the kidneys). When taken by inhalation they attach to receptors in the airways and cause a reduction in lung inflammation, which makes breathing easier. They are usually taken via inhalers which either contain a corticosteroid alone or a corticosteroid in combination with another medicine (such as a long-acting beta₂ agonist). Beclomethasone, budesonide, flunisolide, fluticasone propionate and fluticasone furoate are corticosteroids authorised and marketed as inhalation formulations for use in COPD. Corticosteroid-containing medicines have been authorised in the EU through central and national approval procedures.



More about the procedure

The review has been initiated at the request of European Commission, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

References

1. Calverley PM, Anderson JA, Celli B, et al. Salmeterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. *The New England journal of medicine* 2007; 356: 775-89.