

Annex III

Amendments to relevant sections of the product information

Note:

These amendments to the relevant sections of the product information are the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

Amendments to relevant sections of the product information

The following information should be implemented in the product information of inhaled corticosteroids with a COPD indication.

The wording should be added to or replace existing text as appropriate for each product. If the current SmPC or package leaflet includes corresponding information in any other sections, it should be deleted in order to avoid repeated or contradictory information.

Summary of product characteristics

- Section 4.4 Special warnings and precautions for use

Pneumonia in patients with COPD

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking, older age, low body mass index (BMI) and severe COPD.

- Section 4.8 Undesirable effects

Tabulated list of adverse reactions

“Pneumonia (in COPD patients)” to be listed as “Common” adverse drug reaction in the “Infections and infestations” SOC.

Package leaflet

- Section 4: Possible side effects

Pneumonia (infection of the lung) in COPD patients (common side effect)

Tell your doctor if you have any of the following while taking <active substance> they could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties