



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
XOLAIR

International Nonproprietary Name (INN): *omalizumab*

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Xolair. The Marketing Authorisation Holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted an extension to the current indication for children between 6 and less than 12 years of age. The complete indication is as follows:

Adults and adolescents (12 years of age and older)

Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who have reduced lung function ($FEV_1 < 80\%$) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)

Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.