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EMA/COMP/11127/2011
Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

Esbriet (pirfenidone) for the treatment of idiopathic pulmonary fibrosis

During its meeting of 8-9 February 2011, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/04/241 for Esbriet (pirfenidone) as an orphan medicinal product for the treatment of idiopathic pulmonary fibrosis. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other satisfactory methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained[1].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Esbriet for 'the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF) in adults'.

This falls within the scope of the product's designated orphan indication, which is: 'treatment of idiopathic pulmonary fibrosis'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2004. Idiopathic pulmonary fibrosis remains a condition that is debilitating in the long term and life threatening due to the severe respiratory complications that shorten life expectancy, with patients surviving on average for two to five years after diagnosis.

Prevalence of the condition

The sponsor provided recent scientific literature on the prevalence of idiopathic pulmonary fibrosis in Europe.

On the basis of the information provided by the sponsor and the knowledge of the COMP, the COMP concluded that the prevalence of idiopathic pulmonary fibrosis remains below the ceiling for orphan designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the

[1] The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with a comparable therapeutic indication cannot be placed on the market.

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prevalence was still estimated to be not more than 3 people in 10,000. This is equivalent to a total of not more than 152,000 people in the EU.

Existence of other satisfactory methods of treatment

The COMP noted that, at the time of the review of the orphan designation, no satisfactory treatments were authorised in the EU for patients affected by this condition. Symptomatic treatments to reduce the inflammation in the lungs were used (such as corticosteroids and medicines that suppress the immune system) and in some patients lung transplantation was performed.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that Esbriet still meets the criteria for designation as an orphan medicinal product and that the medicine should remain in the Community Register of Orphan Medicinal Products.

Further information on the current regulatory status of Esbriet can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.