EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/8096/2014
Committee for Medicinal Products for Human Use (CHMP)

Azilect

International non-proprietary name: rasagiline

Procedure No.: EMEA/H/C/000574/PSUV/0060

Period covered by the PSUR: 3 January 2010 to 2 January 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Azilect, the scientific conclusions of PRAC are as follows:

Following the review of spontaneously reported cases of symptoms related to impulse control disorders (ICD), the PRAC noted that the majority of the cases involved concomitant use of dopamine agonists, which is a risk factor for developing ICD. However, there were 8 cases with no associated concomitant drugs and therefore the PRAC considered that a causal relationship between the occurrence of ICD and the use of rasagiline could not be excluded. Taking into account the CHMP/PhVWP conclusions from July 2012 recommending harmonised wording on the risk of ICD for medicinal products containing levodopa, dopamine agonist and/or COMT inhibitors as well as the specific adverse event profile reported for rasagiline, the PRAC recommended the update of SmPC sections 4.4 and 4.8 to inform healthcare professionals, patients and carers that post-marketing cases of ICD have been reported in patients taking rasagiline and to provide advice for monitoring the patients. Furthermore, based on spontaneous reports relating to blood pressure decreases received during the PSUR period, the PRAC considered that a warning on hypotensive effects should be added to SmPC section 4.4 as Parkinson's disease patients may be particularly vulnerable to the adverse effects of hypotension due to existing gait issues. Finally, the PRAC recommended to add a warning to SmPC section 4.4 on the risk of exacerbated dopaminergic side effects and worsening of pre-existing dyskinesia when rasagiline is used in combination with levodopa.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Azilect the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing the active substance rasagiline is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.