05 September 2013
EMA/55354/2014
Committee for Medicinal Products for Human Use (CHMP)

Kalydeco

International non-proprietary name: ivacaftor

Procedure No. EMEA/H/C/002494/PSUV/0008

Period covered by the PSUR: 23-07-2012 – 23-01-2013

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 Kalydeco, the scientific conclusions of PRAC are as follows:

Nearly 15% of the ADRs reported during the PSUR covering period were related to rash. All of them were non-serious. In addition, 3 serious cases were reported from clinical studies. Also 7% of the ADRs reported during the PSUR covering period were related to dizziness and syncope. All of them were non-serious. In addition, 2 serious cases of syncope were reported from clinical studies. Finally 20% of the ADRs reported during the PSUR covering period were related to headache. One of them was serious requiring hospitalization. In addition, 5 serious cases were identified in clinical studies. To conclude serious cases of headache, dizziness and rash have been reported during the PSUR covering period. However, these adverse reactions are currently described in section 4.8 of the SmPC as being mild to moderate in severity, none being serious and that no patients discontinued treatment because of these adverse reactions. Therefore, in view of available data, the PRAC considers that changes to the product information are warranted.

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 Kalydeco the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ivacaftor is favourable subject to the proposed changes to the product information.

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