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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Medicinal product no longer authorised

Active substance(s): eluxadoline

Procedure No. EMEA/H/C/PSUSA/00010528/201703

Period covered by the PSUR: 19 September 2016 – 18 March 2017

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Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for eluxadoline, the scientific conclusions of CHMP are as follows:

During the period under review, there were cases of pancreatitis in patients treated with eluxadoline. Eluxadoline is currently contraindicated in patients without gallbladder and in patients with known or suspected biliary duct obstruction. There was a case of pancreatitis in an 80-year old female patient with gallstones. As a consequence, PRAC proposes to provide more precise information in section 4.3 of SmPC to add list of conditions that predispose to the obstruction of the biliary tree and/or pancreatic duct (gallstones, tumour, periampullary duodenal diverticulum). In section 4.4 subheading *pancreatitis*, the PRAC proposes to revise the information to reflect current data on pancreatitis related to eluxadoline gathered during the reporting period. Two cases were fatal. On the other hand, the majority of cases of pancreatitis occurred within one week, after the first doses. The proposed warning will better reflect characteristics of pancreatitis cases reported. It is also proposed to amend section 4.2 by adding a recommendation that the product should be initiated and used under supervision of physician experienced in management of gastrointestinal disorders in order to minimise the risk of pancreatitis related to eluxadoline use.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing eluxadoline, Annex IIB and a Direct Health Care Communication (DHPC) were warranted.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for eluxadoline the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing eluxadoline is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.

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