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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)

Active substance(s): obeticholic acid

Procedure No. EMEA/H/C/PSUSA/00010555/201706

Period covered by the PSUR: 12 December 2016 - 11 June 2017

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Scientific conclusions

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

In the post marketing setting, serious liver injury and death have been reported with more frequent dosing of obeticholic acid than recommended in patients with moderate to severe decreases in liver function. A causal relationship can currently not be excluded. Liver-related adverse events have occurred both early in treatment and after months of treatment. Hepatically impaired PBC patients with cirrhosis or elevated bilirubin are most at risk of liver related complications.

Reinforced differential dosing recommendations for OCALIVA in primary biliary cholangitis (PBC) patients with moderate and severe hepatic impairment have been recommended in the product information and RMP. A DHPC and a communication plan have been also recommended. 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 obeticholic acid the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing obeticholic acid 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.