16 June 2017
EMA/389173/2017
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): bedaquiline

Procedure No. EMEA/H/C/PSUSA/00010074/201609

Period covered by the PSUR: 06 March 2016 to 05 September 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Results from a published article by Pandie et al show that the bedaquiline exposure (area under curve:AUC) over 48 hours was increased 2 times in subjects treated with bedaquiline as part of therapy for drug-resistant tuberculosis and lopinavir/ritonavir-based antiretroviral therapy.

In view of the data presented in this PSUR, the PRAC considered that changes to the product information of Sirturo were warranted. Based on the safety review, the PRAC considers that an update of the Product Information is necessary in order to add information about bedaquiline exposure over 48 hours in subjects treated with bedaquiline as part of drug –resistant tuberculosis and lopanivir/ritonavir- based antiretroviral therapy in section 4.5 of the Summary of Product Characteristics.

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 bedaquiline the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bedaquiline 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.