EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): efavirenz

Procedure No. EMEA/H/C/PSUSA/00001200/201804

Period covered by the PSUR: 17 April 2017 to 16 April 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for efavirenz, the scientific conclusions of the CHMP are as follows:

For the drug-drug interaction with etonogestrel implant, the PRAC noted the available data from 16 case reports and the published literature articles by *Vieira et al.,* 2014 and *Chappel et al.*, 2017. Based on this new data, the PRAC considers that the statement that the interaction between etonogestrel and efavirenz has not been studied is no longer valid and that this statement should be removed from the SmPC of all efavirenz-containing products.

In view of the data presented in the reviewed PSURs, the overall risk-benefit balance of efavirenz is therefore considered unchanged in the approved indications provided that the terms of the marketing authorisations are varied as relevant.

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

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for efavirenz, the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing efavirenz is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.