25 March 2021
EMA/289786/2021
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): buprenorphine (all formulations except for implant)

Procedure No. EMEA/H/C/PSUSA/00000459/202007

Period covered by the PSUR: 31/07/2017 to 30/07/2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for buprenorphine (other formulations except for implant), the scientific conclusions of the CHMP are as follows:

In view of available data on central sleep apnoea (CSA) from spontaneous reports and relevant literature, the LMS considered that a causal relationship between medicinal products containing buprenorphine and the risk of central sleep apnoea is at least a reasonable possibility. Therefore, the LMS concluded the PI of products containing buprenorphine should be amended accordingly.

In view of available data on skin reactions such as application site discolouration and dermatitis contact from spontaneous reports and relevant literature, the LMS considered that a causal relationship between these reactions and the use of medicinal transdermal products containing buprenorphine is at least a reasonable possibility. Therefore, the LMS concluded the PI of transdermal products containing buprenorphine should be amended accordingly.

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 buprenorphine (other formulations except for implant) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing buprenorphine (other formulations except for implant) 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.