28 January 2021
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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): fentanyl (transmucosal route of administration)

Procedure No. EMEA/H/C/PSUSA/00001369/202004

Period covered by the PSUR: 28 April 2017 To: 28 April 2020

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## Scientific conclusions

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

In view of available data on risk of central sleep apnoea from scientific literature, the PRAC Rapporteur considers that a causal relationship between medicinal products containing fentanyl and the risk of central sleep apnoea is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of fentanyl containing products should be amended accordingly.

In view of available data on risk of Cheynes Stokes respiration in a context of overdose from spontaneous reports including in 2 cases a close temporal relationship and a positive dechallenge, the PRAC Rapporteur considers that a causal relationship between medicinal products containing fentanyl (transmucosal route of administration) and the risk of Cheynes Stokes respiration in a context of overdose is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of fentanyl containing products should be amended accordingly.

In view of available data on nasal burning as local site reaction from spontaneous reports including in some cases a close temporal relationship, the PRAC Rapporteur considers that a causal relationship between the use of PECFENT and "nasal burning" as local site reaction is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of PECFENT 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 fentanyl (transmucosal route of administration) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fentanyl (transmucosal route of administration) 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.