Communication of the President of the Office of 21st May 2024 on the PRAC Committee's recommendation to suspend marketing authorizations for medicines containing 17-hydroxyprogesterone capronate (17-OHPC) in the European Union.

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EMA’s safety committee (PRAC) has recommended the suspension of the marketing authorisations for medicines containing 17-hydroxyprogesterone caproate (17-OHPC) in the European Union (EU). A review by the PRAC concluded that there is a possible but unconfirmed risk of cancer in people exposed to 17-OHPC in the womb. In addition, the review considered new studies, which showed that 17-OHPC is not effective in preventing premature birth. There are also limited data on its effectiveness in other authorised uses.

In some EU countries, 17-OHPC medicines are authorised as injections to prevent pregnancy loss or premature birth in pregnant women. They are also authorised for the treatment of various gynaecological and fertility disorders, including disorders caused by a lack of a hormone called progesterone.

In view of the concern raised by the possible risk of cancer in people exposed to 17-OPHC in the womb, together with the data on the effectiveness of 17-OHPC in its authorised uses, the PRAC considered that the benefits of 17-OHPC do not outweigh its risks in any authorised use. The Committee is therefore recommending the suspension of the marketing authorisations for these medicines. Alternative treatment options are available.

The PRAC also discussed a direct healthcare professional communication (DHPC) for 17-hydroxyprogesterone caproate medicines.

The DHPC will inform healthcare professionals of the PRAC’s recommendation to suspend the marketing authorisations of these medicines in the EU.

The DHPC will also advise healthcare professionals to consider alternative treatment options for any indication.

The DHPC for 17-hydroxyprogesterone caproate medicines will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). When adopted, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

More information available on the website: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-13-16-may-2024 [1]

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President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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[1] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-13-16-may-2024