EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B5 – Medicines – policy, authorisation and monitoring
Head of unit

Brussels, 6 April 2021

NOTE TO THE MEMBERS OF THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE/STANDING COMMITTEE ON VETERINARY MEDICINAL PRODUCTS

Subject: **Adoption of COMMISSION IMPLEMENTING DECISION amending the marketing authorisation granted by Decision C(2010)6109 for "PecFent - Fentanyl ", a medicinal product for human use following an assessment of a periodic safety update report under Article 28 of Regulation (EC) No 726/2004**

EU/1/10/644 - EMEA/H/C/PSUSA/00001369/202004

IMPORTANT:

- Please note that due to the COVID-19 pandemic, the original, signed paper version of the Commission decision and associated annexes will not be sent to marketing authorisation holders by courier. **It will be only sent by a separate e-mail than this adoption fax that will have a request to acknowledge the reception of the documents.**
- Please ensure that someone is available to access the contact e-mail address you have supplied to the European Medicines Agency and to send an acknowledgement of receipt of the documents. Please check e-mails regularly if you are expecting to receive a Commission decision.

The Commission has adopted the abovementioned Decision on 31 March 2021.

The Decision will be notified forthwith to the addressee(s) of the Decision.[1]

The Decision is going to be published for information in all official languages of the EU in the Union Register of Medicinal Products (http://ec.europa.eu/health/documents/community-register/index_en.htm) after the Decision has been notified. The attention has to be drawn to the fact that, under the general rules of the EC Treaty, a Decision is a legal act whose publication is not obligatory in order to be binding.

[1] In case of centralised procedure: Marketing Authorisation Holder; In case of referral or PSUR (Periodic Safety Update Reports) procedures: Member States (via the Permanent Representations to the European Union)

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Cc: Marketing authorisation holder (Contact person, only in centralised procedure);

EMA (Product team leader, secretary)