Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions
Taking into account the PRAC Assessment Report on the PSUR(s) for fentanyl (transdermal patches, solution for injection - nationally authorised product only), the scientific conclusions are as follows:

Dependence and addiction are important risks of fentanyl (transdermal patches - nationally authorised product only) and remain of concern in EU/EEA. The reporting rate did not decrease in current PSUSA period, in general it remained stable of the last 5 years (01 May2019 to 30 April 2024). From literature, several published studies confirm increasing use of opioid-containing medicines in the EU/EEA, although trends may vary across individual member states (e.g., Kalkman et al. 2019, Häuser et al. 2020, Pierce et al. 2021). There are signals of problematic chronic and/or high dose opioid use in EU (e.g., Ellerbroek et al. 2024, Schrader et al. 2024, Vincent et al. 2024). In a recent cross-sectional survey study in the Netherlands (e.g., Jansen-Groot Koerkamp et al. 2024), among general practitioners' and community pharmacists, the majority of respondents agreed that too many opioids are used in the treatment of chronic non-malignant pain and that there are concerns about the addictive potential of opioids. There is also evidence suggesting that in some EU/EEA countries there is increase in opioid-related harm (e.g., di Gaudio et al. 2021, Häuser et al. 2020, Pierce et al. 2021).

The PRAC concluded that the product information of products containing fentanyl (transdermal patches - nationally authorised product only) should be amended accordingly.

No amendments of the product information of fentanyl solution for injection are considered warranted.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for fentanyl (transdermal patches, solution for injection - nationally authorised product only) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fentanyl (transdermal patches, solution for injection - nationally authorised product only) is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Package Leaflet

Section 2

A boxed warning should be added directly under the subheading 'Dependence and addiction', as follows:

Dependence and addiction

This medicine contains fentanyl, which is an opioid. It can cause dependence and/or addiction.

Repeated use of <product name> can also lead to dependence, abuse and addiction which may result in life-threatening overdose.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	26/01/2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27/03/2025