# 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:

In view of available data including two strong literature cases and a plausible underlying mechanism, the PRAC considers that a causal relationship between fentanyl containing products part of this PSUSA and dysphagia is at least a reasonable possibility and the product information of fentanyl transdermal patches and fentanyl solution for injection should be amended.

The CMDh 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 (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 reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing fentanyl (transdermal patches, solution for injection - nationally authorised product only) are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

# 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~~)

**Summary of Product Characteristics**

Section 4.8

The following adverse reaction should be added under the SOC Gastrointestinal disorders with a frequency uncommon:

**Dysphagia**

**Package Leaflet**

Section 4

The following adverse reaction should be listed under the adverse reactions with a frequency uncommon:

**Difficulty in swallowing.**

## Annex III

## Timetable for the implementation of this position

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|---|---|
| Adoption of CMDh position: | December 2023 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 28 January 2024 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 28 March 2024 |