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 nefopam, the scientific conclusions are as follows:

In view of available data on the literature and spontaneous reports, the PRAC considers a causal relationship between nefopam and drug dependence is at least a reasonable possibility. The PRAC concluded that the product information of products containing nefopam should be amended accordingly.

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 nefopam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nefopam is unchanged subject to the proposed changes to the product information
The CMDh recommends that the terms of the marketing authorisations 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~~)

Summary of Product Characteristics

- Section 4.4

A warning should be amended as follows (existing wording on the concerned topic should be replaced by the following paragraph as appropriate):

~~Cases of nefopam dependence and abuse have been reported with nefopam use.~~

Drug dependence

Use of nefopam may lead to drug dependence, which may result in drug abuse, particularly in patients with a history of substance use and/or mental health disorders. In such patients, nefopam should be prescribed with caution, and signs of dependence should be monitored.

- Section 4.8

The following adverse reaction(s) should be added under the SOC Psychiatric disorders: **PT Drug dependence.** with the frequency '**Rare**'

The following paragraph should be added under the table or description summarising the side effects:

Drug dependence

Use of [product name] can lead to drug dependence. The risk of drug dependence may vary depending on a patient's individual risk factors (see section 4.4).

Package Leaflet

- Section 2

Use of [product name] may lead to dependence and abuse. If you have concerns that you may become dependent on [product name], it is important that you consult your doctor.

- Section 4

Rare (may affect up to 1 in 1,000 people):

- **becoming dependent on [product name] (drug dependence).**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25/01/2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26/03/2026