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 paracetamol / pseudoephedrine, the scientific conclusions are as follows:

In view of available data on risk of abuse from the literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between paracetamol/pseudoephedrine and the risk of abuse is at least a reasonable possibility. The PRAC concluded that the product information of products containing paracetamol/pseudoephedrine 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 paracetamol / pseudoephedrine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing paracetamol / pseudoephedrine 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~~)

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

Risks of abuse

Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 4.2).

Package Leaflet

2. What you need to know before you take [drug name]

One of the active ingredients in [drug name], pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more [drug name] than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	7 April 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	6 June 2024