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 pipamperone, the scientific conclusions are as follows:

In view of available data on 'weight increased' and 'increased appetite' from spontaneous reports, including four cases with a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pipamperone and 'weight increased' and 'increased appetite' is at least a reasonable possibility. The PRAC concluded that the product information of products containing pipamperone 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 pipamperone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing pipamperone 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 4.8 Undesirable effects

The following adverse reactions should be added under the SOC 'Metabolism and nutrition disorders' with a frequency 'not known':

Weight increased

Increased appetite

Package leaflet

Section 4. Possible side effects

Not known: frequency cannot be estimated from the available data:

Weight increased, increased appetite

In view of available data from literature, the PRAC considers that a causal relationship between pipamperone and risks of long-term use in the paediatric population is at least a reasonable possibility. Therefore, the PRAC concluded that the product information (PI) of medicinal products containing pipamperone authorised for the use in children and adolescents under 18 years should be amended. MAHs should adapt the text below to their individual medicinal products, considering the wording already implemented in their national PIs, as applicable. If an existing PI wording is stricter, it should be kept.

Summary of Product Characteristics

Section 4.4 Special warnings and precautions for use

A warning should be added as follows:

~~Children and adolescents below 18 years old~~ **Paediatric population**

Clinical response and the need to continue treatment should be re-assessed early after treatment initiation. In patients requiring treatment beyond the acute phase, the benefits and risks should be continuously assessed and the need for continued treatment reviewed regularly.

Package leaflet

Section 3. How to take/use X

Use in children and adolescents

Early after treatment has started, your child's doctor will check whether pipamperone is working well enough and whether your child still needs it. If continued treatment is needed, your child's doctor will regularly check whether pipamperone is still helping and whether it is still necessary.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 August 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 October 2026

APPENDIX I

PRAC PSUR Assessment Report