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 caffeine / dimenhydrinate, dimenhydrinate, the scientific conclusions are as follows:

A. In view of available data on drug abuse spontaneous reports compatible with abuse and high-dose toxicity of dimenhydrinate, consistent with published evidence on misuse/abuse, the PRAC concluded that the product information of products containing dimenhydrinate and caffeine/dimenhydrinate should be amended accordingly.

B. In view of available data on Stevens–Johnson syndrome (SJS) spontaneous reports including one case with positive rechallenge and dechallenge, the PRAC concluded that the product information of products containing dimenhydrinate and caffeine/dimenhydrinate should be amended accordingly.

C. In view of the available data on fixed drug eruption (FDE) including one case with positive recurrence confirmed by provocation test, the PRAC concluded that the product information of products containing dimenhydrinate and caffeine/dimenhydrinate should be amended accordingly.

D. In view of the available literature data on a potential for additive anticholinergic effects with anti-parkinsonian antimuscarinics and other anticholinergic medicinal products, the PRAC concluded that the product information of products containing dimenhydrinate and caffeine/dimenhydrinate 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 caffeine / dimenhydrinate, dimenhydrinate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing caffeine / dimenhydrinate, dimenhydrinate 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~~)>

Drug abuse

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows: (To note that existing wording should be replaced by the following paragraph, as appropriate; unless approved wording is more restrictive):

The following changes to the product information of medicinal products containing the active substance <name of active substance> are recommended (new text underlined and in bold, deleted text ~~strike through~~):

Cases of abuse have been reported with dimenhydrinate, mainly among adolescents or young adults. In patients suffering from psychotic disorders or with a history of abuse and/or dependence, dimenhydrinate should be used with caution. Before prescribing dimenhydrinate to these patients, the patient's risk of abuse should be carefully evaluated.

Package leaflet

- Section 2

Warnings and precautions

Talk to your doctor before taking dimenhydrinate[/caffeine] if you have a psychotic disorder or have a history of substance abuse and/or dependence. You may have a greater risk of abuse/dependency with dimenhydrinate.

Do not take/use more than the recommended dose and do not use this medicine for reasons other than those described in this leaflet.

Stevens-Johnson syndrome (SJS)

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

The following changes to the product information of medicinal products containing the active substance <name of active substance> are recommended (new text underlined and in bold, deleted text ~~strike through~~):

Severe cutaneous adverse reactions (SCARs)

Stevens-Johnson syndrome (SJS), which can be life-threatening or fatal, have been reported in association with dimenhydrinate treatment (see section 4.8).

Patients should be advised of the signs and symptoms of the severe cutaneous adverse reactions and should seek medical advice from their physician immediately when observing any indicative signs or symptoms.

If signs and symptoms suggestive of these reactions appear, *{(Invented) name}* should be withdrawn immediately and an alternative treatment considered (as appropriate).

If the patient has developed a severe cutaneous adverse reaction such as SJS with the use of dimenhydrinate, treatment with *{(Invented) name}* must not be restarted in this patient at any time.

- Section 4.8

The following adverse reactions should be added under the SOC Skin and subcutaneous tissue disorders with a frequency “not known”:

Stevens-Johnson syndrome (SJS)

Package Leaflet

- Section 2

Warnings and precautions

Do not take {(Invented) name}

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking this medicine.

Warnings and precautions

This medicine can cause serious skin reactions. Stop taking {(Invented) name} and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

- Section 4

Stop taking {(Invented) name} and seek medical attention immediately if you notice any of the following symptoms of serious skin reactions:

Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms: (Stevens-Johnson syndrome (SJS)

Fixed Drug Eruption

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders with a frequency “not known”:

Fixed Drug Eruption

Package Leaflet

- Section 4

An allergic skin reaction that may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

Fixed drug eruption usually reoccurs at the same site(s) if the medication is <taken> <used> again.

Patients with Parkinson disease

Summary of Product Characteristics

- Section 4.5

The anticholinergic effect of dimenhydrinate may be potentiated by the concomitant administration of other substances with anticholinergic effects.

Package Leaflet

- Section 2

Other medicines and dimenhydrinate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially if you are taking:

- medicines used to treat Parkinson's disease

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	6 September 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	5 November 2026