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 gabapentin, the scientific conclusions are as follows:

In view of available data on withdrawal reactions following dose reduction from the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between gabapentin and withdrawal reactions following dose reduction is at least a reasonable possibility. The PRAC concluded that the product information of products containing gabapentin should be amended accordingly.

In view of available data on exacerbation of myasthenia gravis from the literature including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action the PRAC considers a causal relationship between gabapentin and exacerbation of myasthenia gravis is at least a reasonable possibility. The PRAC concluded that the product information of products containing gabapentin 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 gabapentin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing gabapentin 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:

Myasthenia gravis
Gabapentin should be used with caution in patients with myasthenia gravis as post-marketing cases of exacerbation of myasthenia gravis have been reported with gabapentin.

A warning should be amended as follows:

Withdrawal symptoms
After discontinuation **or dose reduction** of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed **(see section 4.8)**. ~~Withdrawal symptoms may occur shortly after discontinuation, usually within 48 hours.~~ **The patient should be informed about this at the start of the treatment.** Most frequently reported symptoms include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise. The occurrence of withdrawal symptoms ~~following discontinuation of gabapentin~~ may indicate drug dependence ~~(see section 4.8)~~. ~~The patient should be informed about this at the start of the treatment~~. If gabapentin should be discontinued **or the dose reduced**, it is recommended this should be done gradually over a minimum of 1 week independent of the indication (see section 4.2).

- Section 4.8

The following adverse reaction(s) should be added under the SOC 'Musculoskeletal and connective tissue disorders' with a frequency 'not known':

Exacerbation of myasthenia gravis

The following information on withdrawal symptoms should be amended:

*After discontinuation **or dose reduction** of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed. Withdrawal symptoms may occur shortly after discontinuation **or dose reduction**, usually within 48 hours ~~Most frequently reported symptoms include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise~~ (see section 4.4). ~~The occurrence of withdrawal symptoms following discontinuation of gabapentin may indicate drug dependence (see section 4.8). The patient should be informed about this at the start of the treatment. If gabapentin should be discontinued, it is recommended this should be done gradually over a minimum of 1 week independent of the indication (see section 4.2).~~

Package Leaflet

The following information should be added/amended:

- Section 2

Talk to your doctor or pharmacist before taking [product name]
(…)

- **If you have myasthenia gravis (a disease causing muscle weakness) because this medicine may make your symptoms worse**

Dependence

Some people may become dependent on [product name] (a need to keep taking the medicine). They may have withdrawal effects when they stop using [product name] **or reduce the dose** (see section 3, "How to take [product name]" and "If you stop taking [product name]"). If you have concerns that you may become dependent on [product name], it is important that you consult your doctor.

- Section 3

If you stop taking [product name]

Do not suddenly stop taking [product name] **or reduce your dose**. If you want to stop taking [product name] **or reduce your dose**, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped **or your dose is reduced,** it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with [product name] **or after reducing your dose**, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping [product name] **or reducing your dose**. If you experience withdrawal effects, you should contact your doctor.

- Section 4

The following adverse reaction(s) should be added with a frequency 'not known'/in section 'After marketing [product name] the following side effects have been reported:':

Worsening of myasthenia gravis (a disease causing muscle weakness)

The following information should be amended:

After stopping a short or long-term treatment with [product name] **or after reducing your dose**, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking [product name]").

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position: Correction of the CMDh position:	October 2025 CMDh meeting February 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 February 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13 April 2026