

**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 nitrous oxide, nitrous oxide / oxygen, the scientific conclusions are as follows:

Based on the review of a confirmed signal with respect to the preferred term “convulsions” proposed by one of the marketing authorization holders in this PSUR, the PRAC considers that the more specific term “generalised seizures” should be added to section 4.8 of the summary of product characteristics, with frequency not known for nitrous oxide, nitrous oxide / oxygen containing medicinal products. The package leaflet is updated accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

### **Grounds for the variation to the terms of the Marketing Authorisation(s)**

On the basis of the scientific conclusions for nitrous oxide, nitrous oxide / oxygen the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nitrous oxide, nitrous oxide / oxygen is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing nitrous oxide, nitrous oxide / oxygen are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

## **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**

The following adverse reaction: **generalised seizures** should be added under the SOC Nervous system disorders with a frequency **not known**

## **Package Leaflet**

### **Section 4**

**Generalised seizures with a frequency not known**

**Annex III**

**Timetable for the implementation of this position**

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Adoption of CMDh position:	January 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	16 March 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	15 May 2019