

**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 for the non-interventional imposed PASS final report for the medicinal product(s) containing the active substance magnesium sulphate heptahydrate, sodium sulphate anhydrous, potassium sulphate and concerned by the PASS final report , the scientific conclusions are as follows:

As part of the initial MA procedure (FR/H/511/01/DC), the MAH Ipsen Pharma committed to conduct a DUS to assess drug utilisation in the real life setting in a representative sample of the European target population. The results showed that among the study population compliance is very satisfactory; no firm conclusion could be drawn in special populations. The final study report has been endorsed by the PRAC, and the related condition of the marketing authorisation has been fulfilled.

Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the conditions of the marketing authorisation were warranted.

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 the results of the study for the medicinal product(s) containing the active substance magnesium sulphate heptahydrate, sodium sulphate anhydrous, potassium sulphate and concerned by the PASS final report , the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) mentioned above is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of the products concerned by this PASS final report should be varied.

**Annex II**

**Conditions of Marketing Authorisation**

**Changes to be made to the conditions of the marketing authorisation(s) of medicinal product(s) containing the active substance magnesium sulphate heptahydrate, sodium sulphate anhydrous, potassium sulphate concerned by the non-interventional imposed PASS final report**

The marketing authorisation holder(s) shall remove the following condition(s) (new text **underlined and in bold**, deleted text ~~strike through~~):

~~The Applicant commits to perform a post authorisation safety study (PASS) to assess drug utilisation in real life setting in a representative sample of the European target population. The applicant will submit a draft study protocol within 3 months after approval, in Q2 2013 in order to be ready at the time of product launch in 2014.~~

**Annex III**

**Timetable for the implementation of this position**

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Adoption of CMDh position:	November 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	3 January 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	4 March 2019