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 Oxcarbazepine, the scientific conclusions are as follows:

In view of available data from the literature on increased risk of infants being small for gestational age, the PRAC considers a causal relationship between oxcarbazepine and increased risk of infants being small for gestational age is at least a reasonable possibility. The PRAC concluded that the product information of products containing oxcarbazepine 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 Oxcarbazepine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing Oxcarbazepine 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 4.6

Pregnancy

Risk related to oxcarbazepine:
There is moderate amount of data on pregnant women (300 - 1000 pregnancy outcomes). However, the data on oxcarbazepine associated with congenital malformation is limited. There is no increase in the total rate of malformations with [product name] as compared with the rate observed with general population (2 - 3%). Nevertheless, with this amount of data, a moderate teratogenic risk cannot be completely excluded. Study results related to the risk of neurodevelopmental disorders in children exposed to oxcarbazepine during pregnancy are conflicting and a risk cannot be excluded.
Data from an observational population-based registry study from the Nordic countries suggests an increased risk for children being born small for gestational age (SGA; defined as birth weight below the 10th percentile for their sex and gestational age) following prenatal exposure to oxcarbazepine. The risk of SGA in children of women with epilepsy receiving oxcarbazepine was 15.2% compared with 10.9% in children of women with epilepsy not receiving an anti-seizure medication.

Package Leaflet

2. What you need to know before you take [product name]

[…]

Pregnancy, breast-feeding and fertility

Pregnancy

[…]

Birth weight

If you use [product name] during pregnancy, your child may be smaller and weigh less than expected at birth [born small for gestational age (SGA)]. Among women with epilepsy, in one study, around 15 out of every 100 children born to mothers who had taken oxcarbazepine during pregnancy were smaller and weighed less than expected at birth, compared to around 11 out of every 100 children born to women not taking anti-seizure medication during pregnancy.

Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take [product name].

Do not stop your treatment with [product name] during pregnancy without first checking with your doctor.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	09 June 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	08 August 2025