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 a-tocopheril, a-tocopherol, vitamin E, the scientific conclusions are as follows:

In view of the available evidence on the risk of coagulation disorders and haemorrhagic events associated with overdose of vitamin E and on the risk of coagulation disorders leading to haemorrhagic events associated with the use of vitamin E in patients with vitamin K deficiency or on concomitant anticoagulant treatment with antagonists of vitamin K, consisting of literature articles and spontaneously reported cases and in view of a plausible mechanism of action and of the fact that this risk is already reflected in the PI of vitamin K antagonists and in some vitamin E containing medicinal products part of this PSUSA procedure, the PRAC considers that a causal relationship between a-tocopheril, a-tocopherol, vitamin E and this risk is at least a reasonable possibility. The PRAC concluded that the product information of products containing a-tocopheril, a-tocopherol, vitamin E 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 a-tocopheril, a-tocopherol, vitamin E the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing a-tocopheril, a-tocopherol, vitamin E 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 Special warnings and precautions for use

A warning should be added as follows:

<Active substance> has been reported to change coagulation parameters (INR, Prothrombin Time) in patients with vitamin K deficiency or on concomitant anticoagulant treatment with vitamin K antagonists, which may increase the risk of haemorrhagic events. The treatment with <active substance> may need to be reconsidered and/or an adjustment of the dose of vitamin K antagonist may be necessary (see section 4.5).

- Section 4.5 Interaction with other medicinal products and other forms of interaction

(An) interaction(s) should be added as follows:

In patients on anticoagulant treatment with antagonists of vitamin K, <active substance> may increase the risk of haemorrhagic events. Caution should be taken during coadministration and dose adjustment of the anticoagulants may be necessary (see section 4.4).

- Section 4.9

The recommendations for overdose management should be added as follows:

In case of overdose, treatment with <active substance> must be discontinued. In patients who are actively bleeding or who have changes in coagulation parameters, specific treatment should be considered.

Package leaflet

Section 2 What you need to know before you take <name of the product>

Warnings and precautions

Consult your doctor or pharmacist before starting to take Vitamine E.

- **Do not take higher doses than recommended.**
- **If you have a vitamin K deficiency, <name of the product> may influence clotting of the blood.**

Other medicines and < name of the product>

Tell your doctor if you are taking

- **oral anticoagulants (medications to make blood more fluid), that belong to the class of vitamin K antagonists, such as acenocoumarol, warfarin, dicumarol and phenprocoumon, as vitamin E increases their effect.**

Section 3 How to take <name of the product>

If you take more <name of the product> than you should

- **you may experience problems with blood clotting or even bleeding.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 August 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 October 2026