**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 varicella vaccine (live), the scientific conclusions are as follows:

In view of the literature case reporting a vaccine-derived varicella infection with fatal outcome in an immunocompromised patient with acute lymphoblastic leukemia on reinduction immunosuppressive therapy, the PRAC considers a causal relationship between Varilrix and the fatal outcome is at least a reasonable possibility, despite the fact that the patient was vaccinated in accordance with the warning for 'Individuals at high risk of severe varicella' as stated in section 4.4 of the SmPC of Varilrix. The PRAC considers that section 4.4 of the Varilrix SmPC should be updated to avoid recommending a waiting period between the discontinuation of immunosuppressive therapy/chemotherapy and the administration of live attenuated vaccines such as Varilrix which might be too short for some patients, as stated in the existing recommendations from several European countries regarding the administration of live attenuated vaccines in immunocompromised individuals.

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 varicella vaccine (live) the CMDh is of the opinion that the benefit-risk balance of the Varilrix is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) for Varilrix 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

The warning on individuals at high risk of severe varicella should be amended as follows:

*Individuals at high risk of severe varicella*

There is only limited data from clinical trials available for Varilrix (+4°C formulation) in individuals at high risk of severe varicella.

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

Immunocompromised patients who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent subjects, therefore some of these patients may acquire varicella in case of contact, despite appropriate vaccine administration. These patients should be monitored carefully for signs of varicella.

~~Should vaccination be considered in individuals at high risk of severe varicella, it is advised that:~~

- ~~maintenance chemotherapy should be withheld one week before and one week after immunisation of patients in the acute phase of leukaemia. Patients under radiotherapy should normally not be vaccinated during the treatment phase. Generally, patients are immunised when they are in complete haematological remission from their disease.~~
- ~~the total lymphocyte count should be at least 1,200 per mm3 or no other evidence of lack of cellular immune competence exists.~~
- ~~vaccination should be carried out a few weeks before the administration of the immunosuppressive treatment for patients undergoing organ transplantation (e.g. kidney transplant).~~

**Annex III**

**Timetable for the implementation of this position**

**Timetable for the implementation of this position**

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|---|---|
| Adoption of CMDh position: | November 2025 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 05 January 2026 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 26 February 2026 |