



# Summary of Investigation Results

## Freeze-dried live attenuated varicella vaccine

November 27, 2018

### **Non-proprietary name**

Freeze-dried live attenuated varicella vaccine

### **Branded name (Marketing authorization holder)**

Varicella Vaccine Live Attenuated “Biken” (The Research Foundation for Microbial Diseases of Osaka University)

### **Indications**

Prevention of varicella and herpes zoster in patients aged 50 years and older

### **Summary of revisions**

“Aseptic meningitis” should be added to the Clinically Significant Adverse Reactions section.

### **Investigation results and background of the revision**

Cases of aseptic meningitis have been reported in patients treated with freeze-dried live attenuated varicella vaccine in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

### **Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years**

A total of 2 cases involving meningitis aseptic have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out.)

Pharmaceuticals and Medical Devices Agency

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**Pharmaceuticals and Medical Devices Agency**

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*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

No patient mortalities have been reported to date.

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