



# Summary of Investigation Results

## Freeze-dried BCG vaccine

### (for percutaneous use)

August 22, 2019

#### **Non-proprietary name**

Freeze-dried BCG vaccine

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

Freeze-Dried BCG Vaccine (for percutaneous use; for single dose) (Japan BCG Laboratory)

#### **Indications**

Prophylaxis of tuberculosis

#### **Summary of revisions**

1. "Systemically disseminated BCG infection" and "osteitis, osteomyelitis, periostitis" in the Important Precautions section should be revised to "BCG infection," and language concerning meningitis should be added.

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

A case of tuberculous meningitis has been reported 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.



*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.*

**Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years**

1 case involving tuberculous meningitis has been reported to date (A causal relationship between the drug and event could not be ruled out.)

No patient mortalities have been reported to date.