



## Summary of investigation results

### Freeze-dried live attenuated mumps virus vaccine

January 9, 2015

#### **Non-proprietary Name**

freeze-dried live attenuated mumps virus vaccine

#### **Brand Name (Marketing Authorization Holder)**

Freeze-dried Live Attenuated Mumps Virus Vaccine “Kitasatodaiichisankyo” (Kitasato Daiichi Sankyo Vaccine Co., Ltd) and Dried Live Attenuated Mumps Vaccine “Takeda” (Takeda Pharmaceutical Company Limited)

#### **Indications**

Prevention of mumps

#### **Summary of revision**

‘Acute pancreatitis’ should be added in the Clinically significant adverse reactions section.

#### **Background of the revision and investigation results**

Cases of acute pancreatitis have been reported in persons injected with freeze-dried live attenuated mumps virus vaccine in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

#### **The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 2 cases of adverse events suggestive of acute pancreatitis have been reported (including a case in which causality could not be ruled out). No fatalities have been reported.