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.