



Summary of investigation results

Influenza HA vaccine

July 7, 2015

Non-proprietary name

Influenza HA vaccine

Brand name (Marketing authorization holder)

- a. Influenza HA Vaccine “KAKETSUKEN” (The Chemo-Sero-Therapeutic Research Institute)
- b. Influenza HA Vaccine “Kitasatodaiichisankyo” Syringe 0.25 mL and 0.5 mL, Influenza HA Vaccine “Kitasatodaiichisankyo” 1 mL (Kitasato Daiichi Sankyo Vaccine Co., Ltd.)
- c. Influenza HA Vaccine “SEIKEN”, Flu-Syringe “SEIKEN” (Denka Seiken Co., Ltd.)
- d. Influenza HA Vaccine “BIKEN”, Flubik HA, and Flubik HA Syringe (The Research Foundation for Microbial Diseases of Osaka University)

Indications

Prophylaxis of influenza

Summary of revision

‘Optic neuritis’ should be added to the encephalitis/encephalopathy and myelitis subsection in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of optic neuritis have been reported in persons injected with influenza HA vaccine in Japan. Following an investigation result based on the opinions of expert advisors and the



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.

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 5 cases of optic neuritis have been reported (including 3 cases for which a causal relationship to the product could not be ruled out). Of the 5 cases, no fatality has been reported.