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.

Summary of investigation results

Influenza HA vaccine

May 9, 2019

Non-proprietary name

Influenza HA vaccine

Branded name (Marketing authorization holder)

a. Influenza HA Vaccine “KMB” (KM Biologics Co., Ltd.)
b. Influenza HA Vaccine “Daiichi Sankyo” Syringe 0.25 mL and 0.5 mL, Influenza HA Vaccine “Daiichi Sankyo” 1 mL (Daiichi Sankyo Co., Ltd.)
c. Influenza HA Vaccine “Seiken” (Denka Seiken Co., Ltd.)
d. Flubik HA, and Flubik HA Syringe, Influenza HA Vaccine “Biken” (The Research Foundation for Microbial Diseases of Osaka University)

Indications

Prophylaxis of influenza

Summary of revision

“Acute generalised examthematous pustulosis” should be added to the language concerning oculomucocutaneous syndrome (Stevens-Johnson syndrome) in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of acute generalised examthematous pustulosis have been reported in persons injected with influenza HA 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.

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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

One case associated with acute generalised examthematous pustulosis has been reported to date. (A causal relationship with the product could not be ruled out for this case.) No patient mortalities have been reported to date.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp