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アクトヒブ® (インフルエンザ菌 b 型結合体ワクチン) の市販直後調査を実施して

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A Note on Early Post-marketing Phase Vigilance for *Haemophilus influenzae* Type b Conjugate Vaccine, ActHIB®

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Summary

Early Post-marketing Phase Vigilance for *Haemophilus influenzae* type b conjugate vaccine, ActHIB®, was conducted from December 2008 to June 2009 based on the "Guideline for Implementation of Early Post-marketing Phase Vigilance (EPPV) for Prescription Drugs (March 24, 2006)." We first implemented information delivery to provide monthly updates on adverse reactions for physicians and pharmacists at all hospitals/clinics where ActHIB® was used. As a rule, the EPPV was conducted by means of visits of medical representatives in accordance with the scheduled frequency of vigilance.

There were 755 reported cases, which showed 1,426 adverse reactions, during the period of EPPV. Serious adverse reactions, which consisted of anaphylactoid reaction, febrile convulsion/convulsion, rash and pyrexia, etc., were reported in 17 cases.

Reported non-serious reactions consisted predominantly of pyrexia (199 cases) and injection site adverse reactions such as injection site erythema (redness) (448 cases) and injection site swelling (438 cases).

Key words

PMS, Early post-marketing phase vigilance, ActHIB, *Haemophilus influenzae* type b conjugate vaccine, Hib vaccine