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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA shall not be responsible for any consequence resulting from use of this English version*

### List of Fatal Case Reports

(as of March 24)

No	Vaccine(1) & Lot #	Vaccine(2) & Lot #	Vaccine(3) & Lot #	Age, Female/Male, Underlying disease	Date of vaccination, Process	Result of Review	Date of Report, Areas, Date of the joint meeting**
1 *	Prevenar (1st Dose) 10G03A	ActHIB (1st Dose) E1235	-	2 Y old, male,	February 28, 2011 He died the day after the vaccination. He was found with his face down in a state of cardiorespiratory arrest.	The autopsy report suggested that he died of respiratory failure due to aspiration. The causality between the vaccination and his death is unclear.	March 2, Takarazuka City, Meeting on March 8

No	Vaccine(1) & Lot #	Vaccine(2) & Lot #	Vaccine(3) & Lot #	Age, Female/Male, Underlying disease	Date of vaccination, Process	Result of Review	Date of Report, Areas, Date of the joint meeting**
2*	Prevenar (1st Dose) 10G03A	-	DPT (Kitasato) (4th Dose) AC014D	1 Y old, female, no underlying diseases	March 1, 2011 She died the day after the vaccination. At midnight, she developed hyperthermia. On the following day, she was found lying with her face down in a state of respiratory arrest during a nap.	The autopsy report shows neither clear cause of death nor causality with the vaccination. Human metapneumovirus was identified by polymerase chain reaction (PCR) in her throat swab. This suggested that she died of acute infection.	March 3, Nishinomiya City, Meeting on March 8
3	Prevenar (2nd Dose) 10E02A	ActHIB (2nd Dose) E1065	DPT(Kitasato) (1st Dose) AM009B	< 6M old, female, no underlying diseases	She died 3 days after the vaccination. In the morning, she was found in a state of respiratory arrest.		March 4,  Meeting on March 8
4*	Prevenar (2nd Dose) 10H01A	ActHIB (2nd Dose) E1234	DPT(Kitasato) (2nd Dose) AM009B	≥ 6M, < 1 Y old, female	March 3, 2011 she died the day after the vaccination. Ill complexion, rolling of the eyes and loss of consciousness were noted at noon.	An autopsy was not performed. Neither cause of death nor causality with the vaccination is clear.	March 4, Kyoto City Meeting on March 8

No	Vaccine(1) & Lot #	Vaccine(2) & Lot #	Vaccine(3) & Lot #	Age, Female/Male, Underlying disease	Date of vaccination, Process	Result of Review	Date of Report, Areas, Date of the joint meeting**
5 *	-	ActHIB (1st Dose) E0770	BCG (1st Dose) KH128	<6M old , male, cyanosis at birth, cardiac tumor (check-up at 3-months old showed no abnormalities), right ventricular hypertrophy etc.	February 4, 2011 He died 2 days after the vaccination. He was found in a state of respiratory arrest in the morning.	An autopsy was not performed. Neither cause of death nor causality with the vaccination is clear.	March 5, Miyakonojo City, Meeting on March 8
6 *	-	ActHIB (1st Dose) E1201	DPT (Kitasato) (2nd Dose) AC014D	≥6M, <1 Y old, male, no underlying diseases	February 15, 2011 He died 7 days after the vaccination. In the morning, he was found lying with his face down in a state of cardiorespiratory arrest.	According to the autopsy report, the cause of death was sudden infant death syndrome. Although norovirus was identified by PCR in his stool on admission to the hospital, no symptoms associated with norovirus infections were reported. The causality between the death and infection was unclear. The causality with the vaccinations is also unclear.	March 9, Kumamoto City

No	Vaccine(1) & Lot #	Vaccine(2) & Lot #	Vaccine(3) & Lot #	Age, Female/Male, Underlying disease	Date of vaccination, Process	Result of Review	Date of Report, Areas, Date of the joint meeting**
7	-	ActHIB (1st Dose) E0558	DPT(BIK EN) 3E12A	<6 M old, male, no underlying diseases	July 26, 2010 She died 3 days after the vaccination. She had tachypnoea at night 2 days after the vaccination. In the middle of the night 3 days after the vaccination, abnormal respiration occurred, followed by respiratory arrest at home.	According to the autopsy report, the cause of death was acute circulatory failure. The causality with vaccination is unclear.	March 23

\*Adverse reaction reports in local governments conducting the project for urgent promotion of vaccination including cervical cancer vaccine. Vaccination before conducting the project is not marked.

No.	Vaccine(1) & Lot #	Vaccine(2) & Lot #	Vaccine(3) & Lot #	Age, F/M, Underlying disease	Date of vaccination, Disease course	Result of review	Date of Report, Areas, Date of Joint meeting**
-	-	ActHIB (2nd Dose) E0770	-	<6M old, M, no underlying diseases,	Nov 25, 2010, M, He died the day after vaccination. He was found in a state of respiratory arrest in the morning.	The cause of death is suspected acute pulmonary oedema or aspiration, but the autopsy was not conducted. A causal relationship to vaccination is not clear.	Nov 1, 2010, -, Meeting on Feb 28

\* \*\*The joint meeting refers to the joint meeting of Subcommittee on Drug Safety of Committee on Drug Safety and Vaccine Adverse Reaction Review Committee for Carcinoma of the Uterine Cervix.