VAERS Line List Report

Report run on: 30 MAR 2010 09:46

NULL

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 380081-1 (D)

Gender **Vaccine Date Onset Date Received Date Status Date** Mfr Report Id **Last Edit Date** Age Days State 13.0 F 17-Jul-2009 08-Aug-2009 22 12-Feb-2010 12-Feb-2010 FR WAES1001USA03765 12-Feb-2010 **VAX Detail:** Site **Type** Manufacturer Lot **Prev Doses** Route Other Vaccine HPV4

MERCK & CO. INC. Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Coma, Death, Dyspnoea, Pyrexia

Information has been received from a physician concerning a 13 year old school girl studying in class nine of health center. On 17-JUL-2009, patient received Symptom Text: first dose of GARDASIL left deltoid. Concomitant medications included chloroquine, RANTAC, paracetamol, "IV fluids RL" and aminophyline drip. During the

process of community mobilization for second dose of GARDASIL the multipurpose health worker was informed that the patient developed fever on 01-AUG-2009 and was treated by local registered medical practitioner (RMP). The patient did not recover and was admitted to the hospital on 08-AUG-2009. On the same day, GENTAMYCIN was given. She developed dyspnoea and went into coma and so was referred and was shifted to another hospital where she expired on 08-AUG-2009 at around 9:00 pm. The cause of death was determined as "death due to viral fever". The information was provided from patient's maternal grandparents as she was staying with them. This event occurred after 23 days of receiving first dose of GARDASIL. The female health worker informed the medical officer in charge and he investigated the death and completed the first information report as per AEFI guidelines. The case sheet mentions as "pyrexia of unknown origin". This information was then communicated to district immunization officer, who determined that the death was not related to the vaccine and

Unknown

Intramuscular

so a decision was taken to close the investigation.

RANTAC; acetaminophen, aminophylline; chloroquine Other Meds:

Unknown Lab Data: Unknown History:

Prex Illness: Prex Vax Illns: Page 2350