CONFIDENTIAL

INTERNATIONAL EVENT REPORT

DESK COPY (Page 1 of 3)

I. EVENT INFORMATION

1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH	2a. AGE	3. SEX	4. - 6. EVENT ONSET
Unknown	Austria		2 M	F	06Oct2009

7. & 13. DESCRIBE EVENT(S)

Sudden infant death syndrome, Product quality issue,

This case was reported by a regulatory authority (AT-Bundesministerium fur Gesundheit und Frauen # AT-BASGAGES-091755) and described the occurrence of sudden infant death syndrome in a 2-month-old female subject who was vaccinated with combined diphtheria, tetanus-acellular pertussis, hepatitis B, inactivated poliomyelitis and Haemophilus influenzae type b vaccine. (Infanrix hexa, GlaxoSmithKline), 10 valent pneumococcal conjugate vaccine (Synflorix) and rotavirus vaccine (non-gsk) (RotaTeq) for prophylaxis.

Subject's medical condition showed nothing suspicious, no basic disease.
No concomitant medication.

On 6 October 2009 at about 11:00 am the subject received 1st dose of Infanrix hexa (intramuscular), 1st dose of Synflorix (intramuscular), 2nd dose of RotaTeq (oral).

(See attached page)

8. - 12. CHECK ALL APPROPRIATE TO EVENT

- [X] PATIENT DIED AS OUTCOME OF EVENT
- [ ] RESULTED IN OR PROLONGED INPATIENT HOSPITALISATION
- [ ] INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY
- [ ] LIFE THREATENING
- [ ] CONGENITAL ANOMALY
- [ ] CLINICALLY SIGNIFICANT / REQUIRED INTERVENTION
- [ ] OTHER

II. DRUG INFORMATION

14. IDENTIFIED DRUG(S) 1) Infanrix hexa Injection A21CA561A (Hepatitis B vaccine + Polio.vaccine inactivated + Tetanus vaccine + Diphtheria toxoid + Haemophilus influenzae ty + Acellular pertussis vax) GlaxoSmithKline

15. DAILY/CUMULATIVE DOSE	16. ROUTE OF ADMINISTRATION	17. INDICATION(S) FOR USE	18. THERAPY DATES (From / To)	19. THERAPY DURATION
Unknown	Intramuscular	PROPHYLAXIS	06Oct2009-06Oct2009	1 Days

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [X] N/A

21. DID EVENT REAPPEAR AFTER REINTRODUCTION? [ ] YES [ ] NO [X] N/A

14. IDENTIFIED DRUG(S) 2) Synflorix Injection ASPNA007AG (Pneumoc.polysac S.Type 1 + Pneumoc.polysac S.Type 4 + Pneumoc.polysac S.Type 5 + Pneumoc.polysac S.Type 6B + Pneumoc.polysac S.Type 7F + Pneumoc.polysac S.Type 9V + Pneumoc.polysac S.Type 14 +

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21. DID EVENT REAPPEAR AFTER REINTRODUCTION? [ ] YES [ ] NO [X] N/A

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

23. OTHER RELEVANT HISTORY

IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER

24. NAME AND ADDRESS OF MANUFACTURER (Include Zip Code)

GlaxoSmithKline

Rue De L'Institut 89,
Rixensart, B-1330, Belgium

B0598135A AT2009/00162

24c. DATE RECEIVED	DATE OF REPORT
29JUN2010	29JUN2010

24d. REPORT SOURCE [ ] HEALTH PROFESSIONAL [ ] STUDY [ ] LITERATURE

25a. REPORT TYPE [ ] INITIAL [X] FOLLOW-UP