CIOMS Suspect Adverse Reaction Report

Baxter Healthcare Corporation

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	4-6. REACTION ONSET Day	Month	Year
GRO-A	UNITED KINGDOM	--	--	--	Unknown	MALE	--	--	--

8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☒ OTHER: Med Significant

7+13. DESCRIBE REACTION(S) (Including relevant tests/lab data)

HIV (HIV infection) — Unknown
Hepatitis C (Hepatitis C) — Unknown

This is an initial spontaneous case report received by Baxter from Bayer Healthcare (Bayer MFR # 200710090BBE) that referred to an adult male patient from the United Kingdom who experienced HIV and Hepatitis C following treatment with Hemofil, Factor IX Baxter and other Factor VIII and Factor IX preparations.

This report is part of a class action complaint received by the Bayer Corporate

Cont.

II. SUSPECT DRUG(S) INFORMATION (Continued)

1. SUSPECT DRUG(S) (include generic name)

HEMOFIL
(FACTOR VIII (ANTIHAEMOPHILIC FACTOR))
Dose, form, route and frequency: Unknown;UNK;UNK;UNK
LOT #UNKNOWN
Therapy Dates: Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☐ UNKNOWN ☒ NA

15. DAILY DOSE	16. ROUTE(S) OF ADMINISTRATION
Unknown;UNK	UNK

17. INDICATION(S) FOR USE

DRUG USE FOR UNKNOWN INDICATION

18. THERAPY DATES (FROM/TO)	19. THERAPY DURATION
Unknown	Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☐ UNKNOWN ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (Exclude those used to treat reaction)

Unknown

23. OTHER RELEVANT HISTORY (e.g diagnosis, allergies, pregnancy with last month of period etc.)

Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER PARENT COMPANY

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015 USA

LICENSE DETAILS	24b. MFR. CONTROL NO.
MAA	2007BH002312

24c. DATE RECEIVED BY MANUFACTURER

12FEB2007

24d. REPORT SOURCE

☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ REGULATORY AUTHORITY

DATE OF THIS REPORT

07MAR2007

25a. REPORT TYPE

☒ INITIAL ☐ FOLLOWUP

7+13. DESCRIBE REACTION(S) (Including relevant tests/lab data) (Continued)

Legal Department on 27-Feb-2006, and forwarded to the Bayer Global Drug Safety on 02-Mar-2006. The specific first contact date for this particular case may have been on an unknown later date if the patient was subsequently added to the class action complaint.
Plaintiffs contend in these lawsuits that in the 1970's and 1980's they contracted HIV and/or HCV and/or HBV as a result of their use of factor concentrates. Plaintiffs from many international countries and the United States have brought these suits in the US against four US companiesthat processed plasmaderived factor concentratesduring the relevant time.
This is the narrative as provided by Bayer:

"This case refers to an adult male from the United Kingdom.

Medical and drug history:
It is unknown whether any concomitant drugs have been given.

Suspect drug(s), timing and conditions surrounding the onset of the reaction(s):
Patient received Factor VIII (Cutter) (factor VIII). Administration dates not reported with an unknown lot, total daily dose not reported. Patient also received Factor IX (Cutter). Administration dates not reported with an unknown lot, total daily dose not reported. Patient also received Factor VIII (Alpha Therapeutic Corporation) (factor VIII). Administration dates not reported with lot UNK, total daily dose not reported. Patient also received Factor IX (Alpha Therapeutic Corporation) (factor IX p behring). Administration dates not reported with lot UNK, total daily dose not reported. Patient also received Factor VIII (Armour Pharmaceutical Company) (factor VIII). Administration dates not reported with lot UNK, total daily dose not reported. Patient also received Factor IX (Armour Pharmaceutical Company) (factor IX p behring). Administration dates not reported with lot UNK, total daily dose not reported. Patient also received Factor VIII (Baxter) (factor VIII). Administration dates not reported with lot UNK, total daily dose not reported. Patient also received Factor IX (Baxter) (factor IX p behring). Administration dates not reported with lot UNK, total daily dose not reported.
The progression of the event(s) and its (their) outcome in the patient:
On an unknown date, patient experienced HIV, and HEPATITIS C considered serious due to important medical event. This case is considered closed and will be re-opened if follow up information is received.

The original reporter's clinical assessment:
For the drug Factor VIII (Cutter) no assessment was given. For the drug Factor IX (Cutter) no assessment was given."

Lab tests unknown

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)
FACTOR IX (BAXTER)
(No Pref. Name)
Dose, form, route and frequency
Unknown;UNK;UNK;UNK
LOT #UNKNOWN

Therapy Dates
Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO
☐ UNKNOWN ☒ NA

15. DAILY DOSE
Unknown;UNK

16. ROUTE(S) OF ADMINISTRATION
UNK

17. INDICATION(S) FOR USE
DRUG USE FOR UNKNOWN INDICATION

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO
☐ UNKNOWN ☒ NA

18. THERAPY DATES (FROM/TO)
Unknown

19. THERAPY DURATION
Unknown

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR VIII (CUTTER) (FACTOR VIII ANTIHEMOPHILIC FACTOR) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR IX (CUTTER) (FACTOR IX COMPLEX HUMAN) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR VIII (ALPHA THERAPEUTIC CORPORATION) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR VIII (ARMOUR PHARMACEUTICAL COMPANY) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION (Continued)

4. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR IX (ALPHA THERAPEUTIC CORPORATION) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION (Continued)

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
FACTOR IX (ARMOUR PHARMACEUTICAL COMPANY) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
(FACTOR IX P BEHRING) (No Pref. Name) Dose, form, route and frequency Unknown;UNK;UNK;UNK LOT #UNKNOWN	Therapy Dates Unknown	☐ YES ☐ NO ☐ UNKNOWN ☒ NA
15. DAILY DOSE Unknown;UNK	16. ROUTE(S) OF ADMINISTRATION UNK	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
17. INDICATION(S) FOR USE DRUG USE FOR UNKNOWN INDICATION		☐ YES ☐ NO ☐ UNKNOWN ☒ NA
18. THERAPY DATES (FROM/TO) Unknown	19. THERAPY DURATION Unknown	

PHARMACOVIGILANCE COMMENTS

Given the paucity of information available in this case, Baxter conservatively assesses this case as related for reporting purposes. This does not necessarily reflect a conclusion by Baxter that the case or information contained within constitutes an admission that the drug caused or contributed to an adverse events(s). The patient received multiple different products any of which might have led to these events.
Deborah Lee,MD,PhD22Feb2007