WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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DRS Information Exchange Service

ALERT No. 43

IMMUNE GLOBULIN INTRAVENOUS (GAMMAGARD®) : WITHDRAWN WORLDWIDE

The manufacturer of an immune globulin intravenous product (Gammagard®: Baxter Healthcare Corporation) has announced, as a precautionary measure, the removal of this product from the worldwide market because of its possible implication in the transmission of hepatitis, including hepatitis C. The product is also distributed as Polygam® by the American Red Cross.

Baxter has recently reported that 8 patients in Spain, 4 in Sweden and 2 in the USA have been found to have been reported with laboratory and/or clinical evidence of hepatitis virus infection after receiving Gammagard®. Additional patients have evidence of hepatitis and remain under study. Analysis has shown that only lots manufactured since September 1992 are implicated. These are identified by lot numbers prefixed 2807 or 2317 followed by six additional identifying characters, e.g. 2807A123AA. The product's catalogue numbers are: 060-246, 060-321, 060-322 and 060-943.

On the basis of the temporal association with product administration, the United States Food and Drug Administration regards a causal relationship as probable. However, no case of viral transmission from this product has been confirmed. The FDA is monitoring Baxter Healthcare's efforts to identify implicated lots of the product and to analyze the laboratory and clinical evidence of infection in the affected patients after use of Gammagard®.

Baxter's immune globulin intravenous products are derived from human blood plasma and are used to treat a number of congenital and acquired immunological abnormalities. A different product, intramuscular immune globulin, is used to help prevent hepatitis A in travellers and for other conditions. There are also specific immune globulins, which are used for more specific medical purposes, such as prevention of Rhesus factor sensitization, tetanus or rabies. None of these products is affected by the action.

All donors of plasma that is used to manufacture injectable products for treatment and prevention of disease are screened to exclude infection with five blood-borne disease agents, including hepatitis C, hepatitis B and human immunodeficiency virus (HIV).

No case of HIV transmission through immune globulin products - whether for intravenous or intramuscular use - has ever been documented. The cases of hepatitis reported by Baxter are the first cases of hepatitis associated with licensed intravenous immune globulin, although a few cases of hepatitis C had previously been linked to unlicensed products given during clinical trials.

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Even though viral infections such as AIDS have never been causally linked to the administration of these or other licensed immune globulin products, as an extra precautionary measure, the FDA has been working with manufacturers to ensure that they develop and adopt viral inactivation processes for these products.

References:

1) FDA Talk Paper T94-14 dated 25 February 1994.

2) "Dear Doctor" letter from Baxter Healthcare Corporation dated 23 February 1994.

3) "Dear Doctor" letter from Baxter Healthcare Corporation dated 9 March 1994.

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