RECENT ASPECTS OF HEPATITIS SAFETY

WITH RESPECT TO KRYOBULIN VAPOUR HEATED

In 1990 Mannucci published the results of retrospective HCV-antibody testing of the sera of the patients enrolled in the Italian multi-centre safety study of 1984 - 1986. (Mannucci et al Thrombosis and Haemostasis 64, 232-234 (1990) - copy enclosed) In this retrospective analysis serum samples from three patients taken at the time of entry into the study were found to be anti-HCV-positive. A historical investigation by the author disclosed that at least two of them had had previous contact with other blood products. One of them had also been positive to hepatitis B markers according to the 1988 publication. (In 1988 Mannucci et al had reported four cases of hepatitis B virus infection in patients included in the multi-centre safety study and the authors had suspected a product relationship despite the arguments against this assumption. See Clinical Expert Report page 9 - Study B2) Since Mannucci confined his rechecking of the virgin status to the anti-HCV-positive patients only, it is not clear to what extent this study as a whole includes reliable data from first exposure patients.

Moreover, recently a press report appeared indicating an extremely high hepatitis B prevalence among Italian hospital staff and thus increasing the probability of horizontal infection in the 4 hepatitis B cases described in the 1988 publication

In view of the above IMMUNO can no longer consider the Italian virus safety study appropriate to document the virus safety of KRYOBULIN VH (see enclosed Letter to the Editor, submitted to Thrombosis and Haemostasis).

Upon termination of the Italian study an international safety study, the International Factor Safety Study (IFSS) was designed to establish the safety of Kryobulin VH with respect to the transmission of hepatitis, in particular hepatitis B. The IFSS was carried out in areas of low endemic hepatitis B prevalence and is based on a larger pool of data both with respect to patients and product batches. In an interim evaluation in May 1990 no cases of hepatitis B had occurred in 18 eligible patients treated with FVIII (17 treated with 20 different batches) or FIX (1). Moreover, retrospective testing of HCV-antibody in 26 patients who had received FVIII (22) and FIX (4) respectively, revealed no case of HCV-seroconversion at months 6 and/or 12 - 14 months post infusion.

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