WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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Information Exchange System

Alert No. 81

Polygeline (Haemaccel® 35) - precautionary recall : hypotension

Hoechst Marion Roussel, Germany. The Federal Institute for Drugs and Medical Devices has issued a Rapid Alert enclosing a notification of a batch recall from the manufacturer of the plasma expander, polygeline (Haemaccel® 35: Hoechst Marion Roussel), after an increased number of reports of hypotension were received following administration.

Some of these reports were described as unusual, describing a rapid fall of blood pressure without signs of allergy. However, a definitive relationship to polygeline has not been clearly established and evaluation and monitoring of these events is ongoing.

A recent *in vitro* coagulation test, which is not part of the normal batch release testing or quality control measures for the product, has demonstrated an unexpected but not fully understood finding indicating an inter-lot variability for some Haemaccel® lots and the latest findings indicate a potential biological relevance.

The manufacturer is therefore initiating a precautionary recall from the many countries throughout the world in which the product is distributed.

Reference: Rapid Alert dated 1 March 1999 from the Federal Institute for Drugs and Medical Devices, enclosing a communication from Hoechst Marion Roussel, 26 February 1999.

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