Plasma Protein Therapeutics Association

PPTA Voluntary Standard
Parvovirus B19

Background

The PPTA member companies are committed to taking all appropriate measures to ensure the quality and safety of plasma therapeutics. In 1999 the PPTA Board of Directors approved a recommendation to develop an industry-wide voluntary strategy on Parvovirus B19. The strategy was adopted on 14 February 2000 (VSWG00020) and widely communicated. In keeping with subsequent recommendations of PPTA's Global Management Committee, the Viral Safety Working Group in cooperation with the PPTA Quality and Regulatory Affairs Committee, has developed a voluntary standard for Parvovirus B19 replacing the voluntary strategy.

The introduction of this voluntary standard is a continuing development in the safety of plasma products based on the current scientific knowledge and the limitations of available technology. It evidences the PPTA member companies' commitment to continue to improve the quality and safety of plasma products.

Introduction

Parvovirus B19 is a small (18-24nm) non-enveloped virus of high thermal stability that is unaffected by solvent/detergent treatment. Parvovirus B19 infection in normal individuals results in an early viremic phase, elaboration of IgM followed by IgG, clearance of the virus and life-long immunity. Symptoms of infection in the normal population range from the common asymptomatic or characteristic erythema to less-common anemia and Rheumatoid-like arthritis. Parvovirus B19 might pose more severe consequences to at-risk populations including immune compromised individuals (chronic infection leading to chronic anemia) and pregnant women (fetal death, hydrops fetalis, myocarditis, and chronic post-natal infection). Plasma fractionation and purification processes, specific virus inactivation/removal procedures, and the presence of neutralizing antibodies may contribute to reduce the risk of Parvovirus B19 transmission by plasma derivatives.

While there are no documented transmissions of Parvovirus B19 by albumin or intravenous immunoglobulins (IVIG), the potential for transmission by clotting factor concentrates exists.

The PPTA voluntary standard is an industry initiative to further reduce the risk of Parvovirus B19 transmission.

Voluntary Standard: Parvovirus B-19

The Parvovirus B19 Standard proposed by the Viral Safety Working Group and endorsed by the PPTA Boards of Directors comprises:

- A NAT in-process control testing program must exist for Parvovirus B19 DNA. The goal of the NAT in-process testing component of the voluntary standard is to further reduce the risk of Parvovirus B19 transmission without affecting current protective antibody titers.

- Incoming plasma will be tested for Parvovirus B-19 DNA beginning no later than 1 July 2001. Plasma that would result in a manufacturing pool exceeding 10^5 IU/mL (0.6-0.8 x 10^4 genome equivalents per mL) will be removed. This testing must take into account the risk of removing Parvovirus B-19 antibody containing units, which are needed for the efficacy of immunoglobulin products and may contribute to the safety of all plasma-derived products.

- No later than 1 July 2002, manufacturing pools prepared from NAT screened incoming plasma will not exceed 10^5 IU Parvovirus* B-19 DNA/mL.