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## PLASMA FRACTIONATION: PROGRESS AND CURRENT ISSUES

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Human plasma is a very complex biological material that comprises over 250 proteins covering a myriad of physiological functions. Several life-threatening injuries, coagulation and immunological disorders are treated by therapeutic proteins that are prepared from large pools of human plasma following an industrial-scale process called plasma fractionation. Plasma fractionation itself is an integrated cracking and purification process of the raw material where sophisticated manufacturing steps comprising various combinations of differential precipitation, chromatography, ultrafiltration, and filtration steps are conducted under highly hygienic conditions to isolate individual protein products. During this process, dedicated steps are carried out to specifically and efficiently inactivate or remove plasma-borne infectious agents like HIV, HCV, HBV, HAV, and parvovirus B19. Investigational studies using spiked TSE agents indicate that several purification steps used in the manufacture of plasma products are also likely to remove prion agents to some extent.

To date, over 20 different types of safe plasma protein therapies are available, and clinical experience show that these products have over the years reached a high level of quality and safety. Plasma fractionation has gradually evolved into a modern, highly professional industry. The collection process of plasma used as raw material for fractionation has to meet strict collection and selection criteria in compliance with local and international regulations, and constitute an integral part of the manufacture of plasma products contributing to products quality and safety. Manufacturing processes of plasma products must meet and be operated in compliance with good manufacturing practices and quality assurance principles. The whole chain of production and clinical use of modern plasma products is under the scrutiny of national and international regulatory authorities.

In the recent years, the plasma industry has had to evolve under the pressure of significant technical, regulatory, and economical requirements and has undergone major structural changes and consolidation, which have led, to some extent, to an impediment to innovation and product developments. The consequences of these technical and structural changes in terms of product quality, cost, and supply will be discussed. In addition, it should be kept in mind that disparate availability of safe plasma products remains largely unaddressed across the world, and that appropriate solutions should be found to improve the situation.