WHO Recommendations for the Production, Control And Regulation of Human Plasma for Fractionation

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Human plasma is a source of important medicinal products which are obtained by a combination of large-scale processing steps known as "fractionation". It is important that these products have an appropriate quality and safety profile.

Recognizing the importance of the provision of safe blood, blood components and plasma derivatives, the 58th World Health Assembly in 2005 (WHA) Resolution 58.13) expressed its support for "the full implementation of well-organized, nationally coordinated and sustainable blood programs with appropriate regulatory systems" and stressed the role of "voluntary, non-remunerated blood donors from low-risk populations". The provision of blood, blood components and plasma derivatives from voluntary, non remunerated donors should be the aim of all countries.

The WHO requirements for the collection, processing, and quality control of blood, blood components, and plasma derivatives were published in 1994.

Numerous developments have taken place since that time, requiring updates of both technical and regulatory guidelines to be made available at the global level. The recently published WHO guidelines on viral inactivation and removal procedures address the measures necessary to eliminate or reduce the risk from blood-borne viruses during the processing of plasma into plasma derivatives.

The present Recommendations are intended to provide guidance on the production, control and regulation of human plasma for fractionation as a source material for plasma derived medicinal products. Such information is necessary for the manufacture of safe plasma derivatives in both developed and developing countries worldwide.

This presentation, by bringing together experience and information, will serve as a guide to blood establishments in their implementation of appropriate procedures for the production and control of the starting

plasma material, and will facilitate the provision of safe fractionated plasma products at the national level. It is intended to assist national (medicines) regulatory authorities in establishing the supervision necessary for assessment of the quality and safety of plasma for fractionation, either prepared locally or imported, and will therefore contribute to improved quality and safety of human plasma products worldwide. Manufacturers of plasma derivatives (fractionators) may use these guidelines when discussing the quality criteria of plasma for fractionation with representatives of blood establishments and
the national regulatory authority. This presentation addresses only human plasma sourced for the manufacture of plasma derivatives. Plasma for clinical use is not discussed, nor is there any consideration of plasma from other species.