GUIDANCE ON INCREASING SUPPLIES OF PLASMA-DERIVED MEDICINAL PRODUCTS IN LOW- AND MIDDLE-INCOME COUNTRIES THROUGH FRACTIONATION OF DOMESTIC PLASMA

World Health Organization

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Guidance on increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma

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PREFACE

Plasma-derived medicinal products (PDMPs) play a major role in health care, including treatment for haemophilia, immune diseases, certain infections, and a variety of other serious conditions. A number of PDMPs are included in the WHO Model List of Essential Medicines, emphasizing their importance in the health system and the need to facilitate access to these products in all countries. However, unequal access globally to PDMPs, especially scarcity in many low- and middle-income countries (LMIC), leaves many patients with severe congenital and acquired disorders without adequate treatment. A major factor limiting the global availability of PDMPs is an inadequate supply of plasma meeting internationally recognized standards for fractionation. In response to this situation, the World Health Assembly in 2010 adopted resolution WHA63.12, which urges Member States "to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it".

Medical treatment using blood components rather than whole blood is gradually increasing in developing countries. This results in production of plasma in excess of clinical need. Such "surplus plasma" recovered from whole blood donations (recovered plasma) could be made available for fractionation into PDMPs to help address unmet patient needs. However, in LMIC, good manufacturing practice often is not in place, rendering recovered plasma unacceptable for fractionation, with considerable wastage of plasma as a result.

The WHO guidance on *Increasing supplies of plasma-derived medicinal products in low- and middle-income countries through fractionation of domestic plasma* provides a strategic framework to assist Member States in increasing their volume of quality plasma for fractionation. The guidance was developed under the WHO Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023 to advance the objective of "functioning and efficiently managed blood services". This guidance is complementary to the WHO guidance on centralization of blood donation testing and processing, which assists Member States in deciding whether to centralize blood donation testing and processing and provides practical guidance in that area. Centralization of blood donation processing can play an important role in increasing the availability of quality plasma for fractionation.

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