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LETTER TO THE EDITOR

# Recovered plasma for fractionation: call for quality standards to end wastage

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Plasma-derived protein therapeutics include coagulation factors and immunoglobulins, which are on the WHO Model List of Essential Medicines [1]. The worldwide demand for plasma-derived products is expanding but their availability in developing economies is inadequate. Due to gaps in Good Manufacturing Practices (GMP), linked to inadequacies of governmental, organizational, infrastructural and technical systems, plasma recovered from the collection of whole blood in most low-medium income countries does not meet the internationally recognized quality and safety requirements of developed economies,[2] making it unsuitable for fractionation [3,4]. Plasma is thus discarded, which is a medically unacceptable and unethical waste estimated to reach over 9 million litres per year and still rising [3]. If qualified, this currently wasted plasma could be used to manufacture safe and effective products to save or improve the quality of life of patients with haemophilia, primary immune deficiency, and many other congenital or acquired diseases associated with a treatable plasma protein deficiency [4]. Therefore, the Working Party on Global Blood Safety of the International Society of Blood Transfusion advocates urgent efforts to enable developing economies to achieve quality standards for production of recovered plasma consistent with internationally accepted requirements for fractionation [5]. Specific efforts are needed to (1) implement national policy and legal frameworks for blood collection; (2) establish a national competent authority capable of overseeing the activities of blood establishments; (3) ensure quality at all stages of donor selection, blood collection, donation testing, component processing, in-process control and storage practices [2]; and (4) provide sufficient financial and skilled human resources for upgrading national requirements for the production of recovered plasma suitable for fractionation, and its quality assurance monitoring. When such requirements are met, plasma could be fractionated by licensed fractionators, located either abroad or locally, for a volume supporting the national clinical needs in plasma products. To ensure optimal allocation of scarce resources at national levels, a realistic action plan should be implemented following critical assessment of the transfusion needs and thorough analyses of the options existing in choice of treatment schemes and therapeutic products. The societal outcomes obtained in implementing such actions are multiple, encompassing improved access to essential plasma-derived medicines, a concomitant upgrade in the quality and safety of blood components for transfusion listed by WHO as essential medicines (red blood cells, platelets, and fresh frozen plasma), enhanced sustainability of blood establishments and reduced wastage of a precious national resource.

For the Working Party on Global Blood Safety of the International Society of Blood Transfusion.

## Conflicts of Interest

The authors declare no conflict of interests.

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