सत्यमेव जयते

National Policy for Access to Plasma Derived Medicinal Products from Human Plasma for Clinical / Therapeutic Use:

Addendum to National Blood Policy 2003

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India's voice against AIDS

Department of AIDS Control
Ministry of Health & Family Welfare,
Government of India

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Foreword

Department of AIDS Control provides guidelines for the blood collection, preparation of blood components and manufacturing of plasma-derived medicinal products (PDMPs) in order to optimize the use of human blood. These guidelines are aligned with National Blood Policy and scaling up of facilities for blood component separation is being established. Thus, increasing volumes of human plasma is being recovered in the blood banks, which has been tested and found safe for clinical use, stored under appropriate conditions.

Plasma has limited utility in its raw form for various coagulopathies, plasma exchange, etc., but is one such important blood component is the raw material for the manufacture of many more lifesaving proteins of immense clinical significance. At present, all the recovered plasma is not being used clinically or for plasma fractionation. The policy aims at enabling the mobilization of this excess plasma stocks from blood banks to the plasma fractionation units in order to obtain higher value products that can be made available for wider and easily accessible clinical use. As these products are not available in adequate quantities, to meet the clinical requirements, huge gap of demand and supply of life saving PDMPs exist in our country.

This policy on unutilized plasma aims at making available, easily accessible and adequate supply of high quality of human plasma derived proteins for clinical/ therapeutic use. Thus a step forward to decrease the gap of demand- supply of PDMP's and bring about self sufficiency in safe blood and blood products, based on voluntary non remunerated blood donors, in due course of time.

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Introduction

The Plasma Policy aims at making available, easily accessible and adequate supply of high quality of human plasma derived proteins for clinical/ therapeutic use. The plasma is prepared as part of safe and quality blood and blood components collected/procured from a voluntary non-remunerated regular blood donor in well-equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions.

Plasma has limited utility in its raw form for various coagulopathies, plasma exchange, etc, but is one such important blood component is the raw material for the manufacture of many more lifesaving proteins of immense clinical significance. Such proteins are known as Plasma Derived Medical Products (PDMPs). Examples of PDMPs include Albumin, coagulant proteins such as FVIII, immunoglobulin's such as IVIG and hyperimmunes products from specialized source plasma HBIg, Tetanus Ig etc. Plasma forms the raw material for the manufacture of Plasma Derived Proteins (PDMPs). Currently plasma derived proteins are manufactured within the country in limited quantity by existing Plasma Fractionation Centres. These centres fractionate the unused plasma recovered from whole blood at various licensed blood component separation units of the country but since the plasma availability in the country is limited, a. significant quantity of PDMPs, plasma or its intermediates are obtained through import from other countries.

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At present, all the recovered plasma is not being used clinically or for plasma fractionation. The policy aims at enabling the mobilization of this excess plasma stocks at the blood banks for fractionation to make some more high value products, which hitherto are not often available in adequate quantities to meet the increasing clinical requirements.

The process of collecting standard plasma and transporting them under optimum conditions for fractionation, identifying critical parameters for safety, ensuring compliance with regulatory requirements, training for the appropriate usage of these products will be covered under this policy. The policy reiterates the endeavor of the government to facilitate supply of affordable products to the needy, regardless of their economic status. The policy will result in a comprehensive way to optimize usage of plasma for the manufacture of high quality blood components, and make our country self-reliant and standardize their availability and utilization through comprehensive, efficient and a total quality management approach.

Objectives of the Policy

To achieve the aim of facilitating national access to Plasma Derived Medical Products (PDMPs) for clinical/therapeutic use, the following objectives are drawn:

1. To reiterate that Government will facilitate availability and utilization of safe and adequate quantity of plasma derived products for clinical/ therapeutic use.
2. To make available adequate resources to develop and organize the plasma/ PDMPs mobilization throughout the country.
3. To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.
4. To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.
5. To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

Objective 1

To reiterate that Government will facilitate availability of safe and adequate quantity of plasma derived products for clinical / therapeutic use.

STRATEGY:

1.1 To augment set up & functioning of Blood Component Separation Units (BCSU), including plasmapheresis, with the help of national and state blood transfusion services in the country in order to optimize recovery and utilization of surplus plasma as raw material for plasma fractionation and manufacturing of PDMPs.

1.2 To establish guidelines for plasmapheresis, to collect source plasma for fractionation.

1.3 To establish a mechanism in place for appropriate transfer of plasma from BCSU to warehouses / Plasma Fractionation Centers (PFC).

1.4 To standardize screening of plasma for infections prior to further processing for fractionation.

1.5 To put in place mechanisms to improve co-ordination and interaction between various BCSU and plasma warehouses/PFCs in order to achieve desired end product quality.

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1.6 To advocate for effective and judicious clinical use of human plasma and PDMPs to minimize unwarranted use of whole blood/ plasma/PDMPs.

1.7 To formulate national guidelines on 'Clinical use of plasma derived products' and update as required from time to time.

1.8 To review plasma (raw material for fractionation)/PDMPs (finished products for clinical use) utilization by various facilities acting as an end user individuals/ organizations.

1.9 To promote interdepartmental activities with all concerned including other Ministries, stakeholders and health programs that would help optimize production & utilization of PDMPS.

1.10 To facilitate access and availability of PDMPs to cater to special requirement including remote locations will be done with closed coordination with DGAFMS.

1.11 To establish evidence based latest technology and time to time upgradation to bring about self-sufficiency for PDMPs.

1.12 To participate in public private partnership/ collaborations to improve production and improve availability of PDMPs.

1.13 To evolve mechanisms for periodical review and evaluate the implementation of the policy across the country.

Objective 2

To make available adequate resources to develop and organize the plasma mobilization throughout the country.

STRATEGY:

2.1 To support/ strengthen the existing network of Blood Transfusion Services (BTS) so as to consolidate and improve blood and plasma donor base, blood componentization and recovery of safe and good quality of plasma.

2.1.1 To allocate resources and funds in existing public health programs as well as advocate for resource allocation by corporate sectors, bilateral/international agencies for plasma mobilization.

2.1.2 To additionally strengthen source plasma collection through licensed plasma collection centers across country existing BCSU/ Apheresis/ Blood banks with capacity of conducting plasmapheresis

2.2 To ensure engagement of trained manpower at all levels to facilitate plasma mobilization

2.3 To ensure proper infrastructure, equipment and transportation facilities to have high quality of plasma.

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2.4 To direct efforts towards recruitment and retention of voluntary, non-remunerated blood donors, through education and awareness programs also incorporating IEC strategies, NGO involvement, special donor registries for hyperimmune products etc. as an integral part of voluntary blood donation programs

2.5 To standardize pricing, with the help of existing policies/ resources, to ensure not for profit but techno-financial viable and self-sustaining mechanisms of various types plasma, used as raw material, and PDMPs.

Objective 3

To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.

STRATEGY:

3.1 Formulate regulations to ensure 80 % componentization of whole blood and mandatory channelization of excess unutilized plasma for fractionation.

3.2 Legislative steps to legalize the collection of source plasma for fractionation and licensing mechanism for establishment of plasma collection centers to collect source plasma.

3.2 To facilitate the regulatory approval of updated methodology with the purpose of increasing plasma recovery from donated blood

3.3 To review the regulatory framework with respect to availability/ manufacturing and distribution of acceptable quality of PDMPs for clinical use.

3.4 To review and update Standards, Drugs & Cosmetics Act/Rules and Indian Pharmacopoeia, with respect to national blood policy, from time to time.

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3.5 To periodically review the existing provisions of prevailing regulatory frameworks as well as introduce stringent penalties for unauthorized/irregular practices in plasma processing and delivery of PDMPs.

Objective 4

To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.

STRATEGY:

4.1 To organize capacity building/exposure visit & hands on training of personnel dealing with plasma fractionation, related to all process and quality aspects.

4.2 To facilitate research in blood components, plasma fractionation and PDMPs in association with recognized national and international bodies including ICMR, DST and DCGI.

4.3 To make available financial support for the conduct of R&D in processing of plasma & PDMPs through various channels.

4.4 To collaborate with industry and academia to launch blood products faster and promote Inter-country and intra-country exchange for training and experience of personnel associated with plasma fractionation.

4.5 To direct efforts towards development of indigenous of kits/ processes and technology, to make them cost competitive.

4.6 To facilitate evidence based practices in research involving utilization of human plasma/ blood, from units unused/ discarded from blood banks due to any reason and evolve a regulatory framework thereof.

Objective 5

To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

STRATEGY:

5.1 To set national quality standards covering all aspects in manpower, equipment, processes, procedures, products and quality systems.

5.2 To articulate a continuous all round improvement program in plasma fractionation as part of quality systems as an endeavor to work towards gold standards.

5.3 To mandate that Plasma Fractionating Centres allocate resources for improving the quality of plasma as a raw material to linked BCSU in form of manpower, equipment, logistics etc.

5.4 To encourage training programs to ensure proficiency, accreditation and other changing quality parameters from time to time.

5.5 To encourage higher standards and uniformity, External Quality Assurance Scheme (EQAS) shall be introduced, through the referral laboratories approved by the National Blood Transfusion Council.

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5.6 To ensure complete process control with sound documentation system, to inculcate data sharing and create opportunities to promote learning and growth.

5.7 To collate and analyze the data and share with all stakeholders, regularly as a part of the larger quality management initiative in the area of plasma fractionation.

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