

DOCUMENT- 9

GUIDELINES ON EXCHANGE OF SURPLUS PLASMA WITH INDIGENOUS FRACTIONATORS.



सत्यमेव जयते

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Government of India

Ministry of Health & Family Welfare

National AIDS Control Organisation

D.O.No.S-12016/01/2012-NACO (NBTC)

Dated 28th Oct.2015

Dear

I am writing this to highlight an important initiative that can lead to increase availability of indigenous plasma products, namely by permitting blood banks with component separation facility to exchange their surplus plasma with indigenous fractionators in the country.

2. You would be aware that there have been reports about surplus plasma being wasted in some blood banks. To obviate this, and to increase the availability of indigenous plasma products, a policy regarding permitting blood banks to provide surplus plasma to indigenous fractionators, to increase availability of these products has been under consideration for some time. The subject was initially considered by a group of experts, and has been approved by the National Blood Transfusion Council in its meeting of 05.08.2015. The Health Ministry has also granted its approval to the new initiative.

3. The permission to allow blood banks to provide surplus plasma to indigenous fractionators in the country would henceforth be under the following conditions.

- I. The fractionators must undertake to fulfill needs of Indian market first and none of products recovered from the Indian plasma should be exported before fulfilling domestic demand.
- II. Uniform exchange value of Rs. 1600/- (Rs. sixteen hundred only) per liter of Plasma was agreed upon.
- III. All blood banks must ensure taking of the informed consent of the blood donor for allowing the use of his blood for fractionation, and derivation of essential plasma derived medicines there from.
- IV. The modalities for use of exchange value would be finalized by the respective State Blood Transfusion Councils and would be primarily directed towards ensuring availability of plasma derived products to patients requiring them. These would include :

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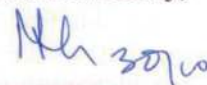
E-mail : nacoasdg@gmail.com

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ
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- a) Buy back of plasma derived products of equivalent value for clinical use by needy patients accessing care at the institution where the blood bank exchanging the plasma is located.
 - b) Receipts of equipment or consumables for strengthening of blood banks capacity and improving component recovery, storage and utilization.
 - c) Any other modality approved by NBTC.
- V. Blood Component Separation Units would directly enter into an agreement with the fractionators, as per mutually agreed terms and conditions approved by respective SBTC before sending plasma for fractionation.
- VI. Feedback would be provided by fractionators to NBTC/ respective SBTC in order to provide evidence of the quality of the plasma being fractionated, so as to enable corrective and preventive action.
- VII. NBTC would review the fractionators periodically so as to prevent any misuse of this strategy.
4. I would seek your personal attention towards successful implementation of this policy.

With regards,

Yours sincerely,


(N.S.Kang)

To,

All Principal Secretary (Health & FW)
& President State Blood Transfusion Council,

Copy for information to :

1. PPS to Secretary Health & Family Welfare, Ministry of Health & Family Welfare, Govt. of India, New Delhi.
2. PPS to Directorate General of Health Services, Govt. of India.
3. Drugs Controller General of India, CDSCO, New Delhi.