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DCGI allows import of plasma to tide over human albumin shortage

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Manufacturers of human albumin are likely to import plasma- a vital blood component to manufacture human albumin, from countries like Vietnam and Sri Lanka to address the shortage of the life-saving human albumin. This is following the Drug Controller General of India (DCGI) approval for import of plasma in view of the shortage.

Human albumin is derived from plasma through a fractionation process. Human albumin serum is a protein in human plasma of the blood which is produced in liver. It maintains levels of calcium in the body and transports nutrients or drugs effectively in the blood stream. The body can suffer a shortage of albumin if a patient is affected by liver disease, kidney failure, burns, malnourishment etc.

Meanwhile, the Union health ministry has also now permitted blood banks having component separation facility to exchange their surplus plasma with indigenous fractionators in the country based on a uniform exchange value of Rs.1,600 per litre of plasma.

Demand for plasma currently stands at over 70,000 vials per month in the country, according to official sources. The manufacturers, however, are able to produce only half of the current demand.

The health ministry's approval is a welcome change to help blood banks provide surplus plasma to indigenous fractionators in the country under the conditions that the fractionators must undertake to fulfill needs of Indian market first. None of the products recovered from the Indian plasma should be exported before fulfilling domestic demand.

According to a senior official, prices of plasma have increased globally because of its increased requirement and therefore it also has a bearing on the cost of life saving human albumin. The current shortage of human albumin in the country can also be attributed to the limited number of plasma fractionation centres in the country, major ones being Navi Mumbai based **Reliance Life Sciences** and Ahmedabad based Intas Pharmaceuticals.

The technology to produce albumin is capital intensive. A fractionation unit costs worth Rs.500 to Rs.600 crore to process 6 lakh litres or even more of plasma to produce the vital human albumin.

Maharashtra Food and Drugs Administration (FDA) has also sent a directive to the blood banks in the state to help manufacturers procure unutilised plasma from the blood banks to address the shortage. There are 309 blood banks across the state of Maharashtra.