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Maha FDA asks Union health ministry to address short supply of human albumin

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To address the shortage of human albumin in the country, Maharashtra Food and Drugs Administration (FDA) is planning to write to the Union health ministry to look into the issues associated with the availability, supply and shortage of human albumin.

Albumin, a component of human blood, is produced by the liver. Its function is to maintain levels of calcium in the body and transport nutrients or drugs through the bloodstream. The body can suffer a shortage of albumin if a patient has liver disease, kidney failure, burns, or malnourishment.

Country's drug pricing regulator - National Pharmaceutical Pricing Authority (NPPA) had also held elaborate discussions with the manufacturers in the past to address the shortage on an urgent basis. The drug pricing regulator has also approached the Union health ministry to look into the issues associated with the availability, supply and shortage of plasma, which is scarcely available and required on a large scale for producing human albumin at an optimum level.

Reliance Life Sciences has also expanded its capacity to one million vials per annum, but it is unable to produce at that level due to limited availability of plasma. Ahmedabad-based Intas Pharmaceuticals and Mumbai-based Reliance Life Sciences are the only two manufacturers producing albumin through their own facilities currently, according to sources.

Reliance Life Sciences is, however, also awaiting central government's approval on imports of plasma required for its production on a large scale. Official sources inform that Reliance is currently supplying human albumin under its brand Albu Rel to limited hospitals based on the demand.

The present supply level of human albumin is around one million vials per annum. Reliance Life Sciences is the major producer accounting for nearly 6 lakh vials per annum. Baxter supplies around 3 lakh vials, which are entirely imported from their principals. The rest account for around one lakh vials. According to an official, "The supply level has not significantly dipped in the past few months, but shortages may be due to supply-gap as compared to demand."

According to stockists, human albumin is currently scarcely available with prices ranging between Rs. 3,897 and Rs. 4,092 for 100 ml respectively. Pharmaceutical companies like Bharat Serums and Baxter were among the major manufacturers, importers and suppliers of albumin in Indian markets.

After slashing of prices by the NPPA, they have stopped supply to domestic markets. NPPA had capped the price of one ml albumin injection of 20 per cent at Rs. 36.66 after bringing it under Drug Price Control Order (DPCO), 2013 to make it affordable to the public.

It has been learnt that there is a huge demand for albumin injections while conducting kidney transplant procedures. Patients' relatives have to make several attempts to procure it. The drug has been in short supply for a long time.

Treatment is compromised because of non-availability of albumin.

Also, after a major surgery, such as kidney or liver transplant, the body does not produce sufficient albumin. Transfusion of human albumin is needed for proper healing, or to reduce water retention and swelling caused in the body due to infection or disease.