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Maharashtra FDA to help blood banks across state to adopt Haemovigilance Programme of India

Shardul Nautiyal, Mumbai, **Tuesday, September 22, 2015, 08:00 Hrs [IST]**

In order to help blood banks across the state to adopt Haemovigilance Programme of India (HvPI) as per the National Blood Policy, the Maharashtra Food and Drug Administration (FDA) will soon roll out a series of workshops in association with the Union health ministry in a couple of months time, according to an official associated with the development.

HvPI is aimed at collecting vital data to increase safety, reliability of the blood transfusion process and introduce required changes in the existing policies. The information will also come in handy in bringing out new guidelines. Even though it is a voluntary exercise, all blood banks and hospitals should adopt this programme as it will ensure patient safety during blood transfusion, a senior official said.

The programme intends to document the blood transfusion chain from blood donors to recipients and to help detect any adverse blood transfusion reaction during its usage. Besides documenting adverse reactions to recipients, haemovigilance helps in getting details pertaining to collection, investigation, its analysis and transfusion of blood or blood components.

Launched by National Institute of Biologicals (NIB) on December 10, 2012, HvPI has till date reported 2700 adverse transfusion reaction reports. Currently, 207 centres have enrolled under HvPI attached to blood banks, government and private hospitals to collect data in transfusion reaction reporting form (TRRF) through a software, Haemo-Vigil, indigenously developed by IT division of NIB. This data is aimed at generating evidence based recommendations for safety related regulatory decisions.

The reporting system under the HvPI is systems oriented, independent of any authority and confidential. It offers expert analysis and is responsive. NIB and Indian Pharmacopoeia Commission (IPC) function as the co- ordinating centre between the reporters and regulators. Reports are evaluated by experts who understand the clinical circumstances and are trained to recognise underlying systems causes through a Haemovigilance Advisory Committee (HAC).

Besides this, the identities of the patient, reporter and institution are never revealed to third party going by the clause for confidentiality. Traceability of events related to blood transfusion is done through proper documentation which in turn leads to effective recommendations to be accepted and acted upon.

According to an expert, HvPI will increase the safety and quality of the entire process from donation to transfusion. It will help improve standards, systems and processes and bring about required changes in the applicable policies, despite being a voluntary exercise.

HvPI is aimed at targeting areas for improvement in practice, stimulating research, raise awareness of transfusion hazard and improves safety of blood transfusion for patients. It is also instrumental in identifying trends in adverse reactions and events, thereby, to form transfusion policy.