Concerns in Access to Safe and Sufficient Blood

What is the issue?

In India regulatory framework must be reformed to ensure access to safe and sufficient blood.

What are the shortfalls in the blood collection in India?

- In 2015-16, India was 1.1 million units short of its blood requirements, there were considerable regional disparities, with 81 districts in the country not having a blood bank at all.
- In April 2017, it was reported that blood banks in India had in the last five years discarded a total of 2.8 million units of expired, unused blood (more than 6 lakh liters).
- Due to practical constraints, tests are only conducted post-collection, and blood donor selection relies on donors filling in health questionnaires truthfully.
- However, these tests are not foolproof as there is a window period after a person first becomes infected with a virus during which the infection may not be detectable.
- This makes it crucial to minimize the risk in the first instance of collection.

What are practical difficulties in collection and storing of blood?

- Blood that is donated voluntarily and without remuneration is considered to be the safest.
- Unfortunately, professional donors (who accept remuneration) and replacement donation (which is not voluntary) are both common in India.
- In the case of professional donors there is a higher chance of there being TTIs in their blood, as these donors may not provide full disclosure.
- In the case of replacement donation, relatives of patients in need of blood are asked by hospitals to arrange for the same expeditiously.
- This blood is not used for the patient herself, but is intended as a replacement for the blood that is actually used.
- In this way, hospitals shift the burden of maintaining their blood bank stock to the patient and her family.
- Here again, there could be a higher chance of TTI’s because replacement donors, being under pressure, may be less truthful about diseases.

What are the issues in regulatory framework of blood banks?

- The regulatory framework which governs the blood transfusion infrastructure in India is scattered across different laws, policies, guidelines and authorities.
- Blood is considered to be a ‘drug’ under the Drugs & Cosmetics Act, 1940.
- Therefore, just like any other manufacturer or storer of drugs, blood banks need to be licensed by the Drug Controller-General of India (DCGI).
- For this, they need to meet a series of requirements with respect to the collection, storage, processing and distribution of blood, as specified under the Drugs & Cosmetics Rules, 1945.
- Blood banks are inspected by drug inspectors who are expected to check not only the premises and equipment but also various quality and medical aspects such as processing and testing facilities.
- Their findings lead to the issuance, suspension or cancellation of a license.
- In 1996, the Supreme Court directed the government to establish the National Blood Transfusion Council (NBTC) and State Blood Transfusion Councils (SBTCs).
- The NBTC functions as the apex policy-formulating and expert body for blood transfusion services and includes representation from blood banks. However, it lacks statutory backing (unlike the DCGI), and as such, the standards and requirements recommended by it are only in the form of guidelines.
- The DCGI does not include any experts in the field of blood transfusion, and drug inspectors do not undergo any special training for inspecting blood banks.
- This gives rise to a peculiar situation, the expert blood transfusion body can only issue non-binding guidelines, whereas the general pharmaceutical regulator has the power to license blood banks.
- This regulatory dissonance exacerbates the serious issues on the ground and results in poor coordination and monitoring.

What measures are needed?

- In order to ensure the involvement of technical experts who can complement the DCGI, the rules should be amended to involve the NBTC and SBTCs in the licensing process.
- Given the wide range of responsibilities the DCGI has to handle, its licensing role with respect to blood banks can even be delegated to the NBTC under the rules.
- This would go a long way towards ensuring that the regulatory scheme is up to date and accommodates medical and technological advances.
- Despite a 2017 amendment to the rules which enabled transfer of blood

between blood banks, the overall system is still not sufficiently integrated.

- A collaborative regulator can, more effectively, take the lead in facilitating coordination, planning and management.
- This may reduce the regional disparities in blood supply as well as ensure that the quality of blood does not vary between private, corporate, international, hospital-based, non-governmental organizations and government blood banks.
- The aim of the National Blood Policy formulated by the government back in 2002 was to "ensure easily accessible and adequate supply of safe and quality blood".
- To achieve this goal, India should look to reforming its regulatory approach at the earliest.

Source: The Hindu