

Common Cause

Vs

Union of India and Others

Writ Petn. (Civil) No. 91 of 1992

(K. Ramaswamy, G.B. Pattanaik JJ)

04.01.1996

JUDGEMENT

S. C. AGRAWAL, J.:-

1. Blood is an essential component of the body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-being. At the same time blood, in stead of saving life, can also lead to death of the person to whom the blood is given if the blood is contaminated. As result of developments in medical science it is possible to preserve and store blood after it has been collected so that it can be available in the case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its components and make the same available when needed. In view of the dangers in supply of contaminated blood it must be ensured that the blood that is available that is available with the blood banks for use is healthy and free from infection

2. In this petition filed by way of Public Interest Litigation under Article 32 of the Constitution the petitioners has high-lighted the serious deficiencies and short-comings in the matter of collection, storage and supply of blood through the various blood centres operating in the country and has prayed that an appropriate writ order or direction be issued directing the Union of India and the States and the Union Territories, who have all been impleaded as respondents in this petition, to ensure that proper positive and concrete steps in a time bound programme are immediately initiated for obviating the malpractices, malfunctioning and inadequacies of the blood banks all over the country and to place before this Court a specific programme of action aimed at overcoming the deficiencies in the operation of blood banks.

3. For the purpose of regulating its collection, storage and supply, blood is treated as a "drug" under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act'). In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as "the Rules") made under the Act, provisions regarding equipment and supplies required for a blood bank were contained in Part XII-B, which was inserted vide Notification dated June 24, 1967. In the said part, requirements regarding Equipment, Blood collection supplies, Canter equipment and Emergency equipment for the Blood Donor Room were prescribed. Similarly provisions were made for the Laboratory, General suppliers, Technical staff, Accommodation for Blood Bank, Lable for whole blood and Colour scheme for Label etc.

4. In 1990, M/s. A. F. Ferguson & Co., a Management Consaltancy Firm, was entrusted by the Government of India, Ministry of Health with the study of blood banking system in the country. The scope of the said study was to :

- i) assess the status of Government, Private, Commercial and Voluntary blood banks;
- ii) recommended policy and procedural changes; and
- iii) prepare a scheme for modernisation;

5. The report submitted by the said consultancy firm to the Government in July, 1990, highlights the deficiencies with regard to the facilities of testing of blood, licensing of blood banks and professional donors and storage of blood. In the said report it was stated :

i) Out of the total number of 1018 blood banks as many as 616 are reported to be unlicensed. There are only 201 licensed commercial blood banks; the supply of blood by licensed commercial blood banks is only about 1/4th of the blood used in the hospitals of the Country.

ii) No medical check up is done on the blood sellers; their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling their blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many persons who donate blood 5-6 times in a month; poverty makes them to do so at first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply.

iii) It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, viral hepatitis, malaria, venereal diseases etc. It is reported that mandatory tests which are required to be done are rarely conducted. Most of the AIDS surveillance centres are not functioning efficiently and up to 85 per cent of blood collected in the country is not screened for AIDS. Under an action plan to screen blood for AIDS 37 blood testing centres were to be set up in 29 cities, but only 11 testing centres were functioning by July, 1990, and training of technicians for these centres was lagging.

(iv) The blood banks presently thrive on bleeding 4000 to 5000 regular professional donors in 18-20 cities. The professional blood donors, which include many, are reported to be victims of ill health, low haemoglobin levels and many infections, and are bled at frequent intervals by the commercial blood banks.

(v) Storage facilities in the blood banks are far from satisfactory. The blood banks have necessarily to possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature for ensuring safety of blood . In the existing blood banks many items of equipment remain unattended for year, electricity failures are frequent, generators are a rarity. This applies not only to commercial blood but even to some of the government hospitals. Many times of the basis equipment needed for blood banks are not available and a good part of them do not have even adequate storage facilities.

vi) Many of the blood banks are located in unhygienic environment and they collect and store blood in very dirty conditions.

vii) In some places strong middle men operate for the blood banks by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the level of health etc.

viii) A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis and AIDS and are unfit to donate blood.

ix) Trained personnel are generally not available in the blood banks. Most of the blood banks lack trained post-graduates at the helm; they have no donor organisers to bring voluntary donors; and many of them are manned by technical staff who do not have requisite qualification of a diploma in Medical Laboratory Technology. At present there is not even a course to provide post-graduate specialisation in the field of blood donation and transfusion as in developed countries. The Drug Control Departments, which are expected to ensure the appropriate functioning of the blood banks, do not themselves have specified trained personnel.

x) In the storage of blood the basic and essential requirement of clean environment, shelf life of blood etc. are ignored. Nexus is reported to be existing between the attending doctor of the patient and the commercial blood bank, with the former directing the patients to the latter, and the latter giving a percentage of the sale to the former.

6. According to the report of M/s. A. F. Ferguson & Co. out of the total number of 1018 blood banks in the country, 203 are commercial blood and the rest controlled by the Central Government, State Governments, Private Hospitals and voluntary organisations. The volume of the blood collected by the commercial blood banks is 4.7 lakhs units out of the total of 19.5 lakhs units by all blood banks and the commercial blood banks and are collecting blood banks mostly from professional donors while the other blood under the control of the State Governments, Central Governments Private organisations and voluntary organisations are collecting blood mostly from the relatives of the patients or from the voluntary donors.

7. In the counter affidavit filed by Dr. Lalgudi Vaidyanathan Kannan, Deputy Drugs Controller, on behalf of the Union of India it is stated that after the receipt of the report of M/s. Ferguson & Co., the Drugs Controller, India, by his letter dated August 23, 1990 asked all the State Drug Controllers (who are the licensing and enforcing authorities under the Act) to ensure that inspections are carried out of all commercial blood banks and unlicensed Government blood banks keeping in view the standards prescribed in the Act and Rules and phased programme of inspection covering first the commercial / private blood and thereafter the Government blood banks and was suggested. It was also suggested that the private / commercial blood banks should not be allowed to operate unless they fulfil all the requirements prescribed in the Rules and each unit of blood is tested for blood transmissible diseases (Hepatitis, HIV, Syphilis etc.) and that unlicensed blood banks are to be licensed only after ascertaining that they conform to the standard laid down under the Rules. It was also suggested to the State Governments the licences of blood banks who do not comply with the provisions of the Rules should be cancelled and the State Drug Controller were asked to send the status reports of blood banks in their respective States. As per the information forwarded by 23 State Governments / Union Territories, about 341 blood banks are unlicensed and most of them are run by Red Cross Societies and Charitable Institutions. In the said counter affidavit mention is also made of the steps that have been taken in the matter of testing of blood for AIDS, storage facilities

in blood banks, for upgradation and modernisation of Government managed blood banks, and training of drugs inspectors and blood banks technical per sonnel.

8. During the pendency of this writ petition action has also been taken to revise the Rules governing the licencing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment) Rules 1982 published in the Gazette of India vide Notification dated January 22, 1993. Part X-B has been inserted in the Rules and Part XII-B has been substituted. In part X-B (Rules 122-F to 122-P) provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood components by blood banks and manufacture of blood products and for grant and renewal of licence for the operation a blood bank / processing of human blood for components / manufacture blood products. Under the said provisions licence and only be granted / renewed with the approval of the Central Licence Authority viz. the Drugs Controller of India. Part-B contains provisions relating to space equipment and supplies required for a Blood Bank.

9. During the course of the hearing of this petition, the petitioner, the petitioner submitted a draft scheme and a scheme was also submitted by the Union of India. In the affidavit filed by Dr. Shiv Lal, Addl. Director, National Aids Control Organisation, along with the scheme, it was stated that the Central Council of Health, in which the State Health Ministers are members, is the highest Forum for Policy frame work and that the said Council has given guidelines in respect of Blood Banks and Transfusion Service and its recommendations are as under :-

"Blood being a vital input in the present day medicare services the acute shortage of which is hampering the effectiveness of our services the joint Conference recommends that urgent steps should be taken by the States / Union Territories Governments and the Central Government.

1. To build up adequate blood banking services at State / District level including provision of trained / qualified man power. Necessary action should be initiated in right earnest for achieving the objective in view.
2. To educate and motivate people about blood donation on a voluntary basis.
3. To provide adequate encouragement to voluntary donors.
4. To enforce quality control of blood in all its facets of collection, distribution and storage.

In the said affidavit it was also state that although the World Health Organisation has prescribed that nearly 40 lakhs units of blood is required for the country, the collection is only 19.5 lakhs units at present and, therefore it is not possible to ban professional donors at this stage unless the donation of blood by way of voluntary donation are increased. In the said affidavit it was further stated that most of the Government Blood Banks are lacking in man powers, training and laboratory facilities to test blood for blood transmissible diseases and to augment this, the Central Government has provided funds to various State Government during 1990-91 and 1991-92 to moderruise Government Blood Banks. According to the said affidavit, the main objective for the modernisation of the Blood Banks have been provided into term objectives and medium term objectives as under:-

"I. Long term objectives :

(a) Make available high quality blood and blood components in adequate quantity to all users.

(b) Ensure wide usage of blood components. (c) Expand voluntary and replacement donor base, so as to phase out professional blood donors.

II. Medium term objectives:

(a) To provide minimum possible facilities for blood collection, storage and testing in all Government Blood Banks.

(b) To make available the trained man-power in all Government Blood Banks.

(c) To ensure the awareness of clinicians and Blood Banks staff on the advantages of blood components.

(d) To ensure the effective geographical coverage keeping in mind the different volumes of blood requirement in different cities.

(e) To increase public awareness about the risks in using blood from commercial Blood Banks and professional donors and the harmlessness of blood donation."

10. On a perusal of the draft scheme that was submitted by the petitioner and the draft scheme submitted by the Union of India, it was felt that it would facilitate matters if the question of necessary steps which may be required for further strengthening the existing frame-work about licensing of blood banks and obtaining blood donations is examined by a Committee which would place its suggestions before the Court for consideration. By order dated 11th February, 1994 a committee of the following persons was constituted to examine the matter and submit its report :

1. Additional Secretary, Ministry of Health holding the charge of Director, National Aids Control Organisation as Chairman.

2. Drugs Controller of India.

3. Mr. H. D. Shourie.

The said committee felt that since Indian Red Cross Society is presently involved to a considerable extent in blood banking operations and it has branches spread all over the country and it has capacity to further strengthen itself for looking after the various aspects of functioning of blood banks, it may be recognised as nodal agency in the field of blood banking and blood transfusion technology in the country. The Committee suggested that detailed discussions to finalise assessments in this regard may be held with the Indian Red Cross Society. Having regard to the said suggestions by the committee constituted by the Court, the Indian Red Cross Society constituted a committee of experts to examine the matter and to prepare a draft blue print. The said committee of experts in its report dated April 15, 1995 has indicated the following fields in which measures are required to be taken:

"1. Building a Powerful voluntary blood donation movement to augment supplies of safe quality blood and blood components.

2. Exercising economy by processing whole blood for blood components.
3. Introducing screening procedure to minimize the danger of transmissible diseases like AIDS. Hepatitis etc.
4. Standardize technological procedures for rigid enforcement of quality control, and good manufacturing practices.
5. Providing technical services for raising the standard of blood centre operations and assistance for administrative, motivational and technical problems encountered."

It has proposed an action plan in three parts : Immediate Plan, Short Term Plan and Long Term Plan, which are as follows:-

"Immediate Plan.

1. To establish an administrative unit at the national headquarters under the charge of a project director.
2. To identify and strengthen a minimum of 2 Red Cross blood centres for each state for augmenting the existing blood programme. Necessary inputs towards staff, equipment and consumables for the development should be made available at once. Basic requirements to procure accreditation from DC(I) should be ensured.
3. Donor recruitment and intensification of donor motivation drive may be taken up on priority basis. Involvement of media may be ensured through Information and Broadcasting Ministry.
4. A crash programme for short term training of medical officers, technicians and medical social workers nurses of concerned centres may be undertaken. This distance learning programme prepared by the WHO may be helpful in updating the knowledge of technologists at the centres being strengthened.
5. In addition to the blood centre, strengthening programme, steps may be taken for planning and initiating action for the establishment of regional blood centres at the following 16 metropolitan cities with 2 million population having many large medical superspeciality institutions

- | | |
|-------------|----------------|
| 1. Delhi | 9. Bhopal |
| 2. Lucknow | 10. Ahmedabad |
| 3. Patna | 11. Bombay |
| 4. Calcutta | 12. Hyderabad |
| 5. Gauhati | 13. Bangalore |
| 6. Cuttack | 14. Trivandrum |
| 7. Nagpur | 15. Madras |

8. Jaipur 16. Chandigarh

Each centre will be expected to collect 150 to 200,000 units annually. These will be screened processed and distributed as blood components to local hospital based centres against service charges. As the regional centres will supplement the blood supplies through the existing system it would help in weeding out the blood from paid blood sellers. Therefore it is of paramount importance that top priority is given for the establishment of these centres.

Short Term Plan :

1. Coordination of the blood programme of large medical colleges having more than 1000 beds and / or collecting over 10,000 units.
2. Establishment of post graduate training centers at places where facilities for fulfilling the norms of the Medical Council of India exist. In the initial stages Faculty support can be obtained from departments of pathology. At the following cities post graduate training can be started :

1. Chandigarh 6. Bombay
2. Delhi 7. Hyderabad
3. Lucknow 8. Bangalore
4. Calcutta 9. Trivandrum
5. Jaipur 10. Madras

Training of paramedical worker can also be undertaken at these centres.

3. Coordination of all other voluntary organisations working for the promotion of the blood programme by the Red Cross Society would further help in achieving the target of donor recruitment with greater vigour and better evaluation.
4. A national workshop at the Red Cross headquarters may be organised for officers of all centres being strengthened and the representatives of regional centres to provide necessary guidance for uniform and standardised and practices.

Long Term Plan :

1. To upgrade all other blood centres.
2. Establishment and upgradation of blood centres in areas where it does not exist.
3. Planning of more regional centres.
4. Establishing fractionation centres.
5. Establishment of therapeutic centres for blood related disorders.

6. Programmes for indigenisation of equipped software and reagents.

7. Establishment of tissue typing facilities for Bone Marrow and organ transplant."

After considering the said report of the committee of experts set up by the Indian Red Cross Society, the committee constituted by the Court submitted its final report which was filed along with the affidavit of Shri Ashwini Kumar, Deputy Drugs Controller of India in the Directorate General of Health Services dated October 26, 1995. The committee has made the following recommendations and has suggested steps for revamping the system of blood banks in the country in the form of plans of implementation on immediate basis and for long term implementation.

FOR IMMEDIATE IMPLEMENTATION :

(i) A National Council on Blood Transfusion should be established. It should consist of Director General of Health Services, Drug Controller of India, representative of Ministry of Finance, high level representatives of Indian Red Cross Society and selected five major medical and health institutions of the country, and three eminent citizens. presided over by the Additional Secretary of the Ministry of Health who is in charge of operations of the programme of National Aids Control Organisation. The Council should be provided the basic secretariat under charge of a Director by the Ministry of Health and be located in suitable premises at Delhi for effective functioning.

It would be desirable to register the Council as a Society under the Societies Registration Act for enabling it to have its own identity and funds and also for enabling it to raise funds from various sources including contributions from trade, industry and individuals. The basic requirements of its functioning should be provided by the Ministry of Health. The Council will be policy formulating body in relation to all matters pertaining to operation of blood banks.

(ii)The Ministry of Health, with the assistance of National Council, will ensure the establishment of State Level Councils, at suitable centers, preferably headquarters at the premises of some outstanding medical institutions or hospitals. The State Councils should have on them representatives of important medical institutions of the State, selected representatives of blood banks of repute, a representative of Red Cross and should include the State Director of Health Services as well as State Drug Controller operating under a designated Director and presided over preferably by the State Government Secretary in charge of health. A representative of the State Ministry of Finance should also preferably be on the Council. The size of State Council should preferably be restricted to the maximum of about 11 members. The Director of Health Services should provide the Committee the basic essentials of secretariat and funds for its functioning. The State Councils, as in the case of National Council, should be registered as Society under the Societies Registration Act for maintaining their identity and for purposes of collection of funds in the shape of contributions from individuals and corporate bodies. The State Councils should endeavour to operate on the basis of policies formulated by the National Council, effectively implementing the policies and programmes formulated by them.

(iii) Programmes and activities of the National Council and State Councils should cover the entire range of services related to operation and requirement of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of blood donation in educational institutions, among the labour, industry and trade, establishments and organisations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation transport, quality control and archiving system, cross-matching of blood between donors and recipients, separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

LONG TERM OBJECTIVES :

i) The programme formulation at the national level and State levels should take into account the requirements of laying down targets for achievement, including the establishment of appropriately designed and equipped blood banks, ensuring that all blood banks are licensed, making satisfactory arrangements for collection and storage of collected blood, fractionalisation of blood into the components, special emphasis will need to be laid in the programme on the attainment of prescribed targets of organising camps for voluntary collection of blood through motivational campaigns and utilisation of the media. The State Councils shall submit their programmes and targets to the National Council and thereafter continue to submit quarterly reports to the Central Council about the fulfilment of the targets relating to the programmes.

ii) The National Council and State Councils should launch effective programmes and organise campaigns for collecting funds for implementation of their programmes, supplementing the funds allotted to them respectively by the Government of India and the State Governments. For the purpose of facilitating the collection of funds for blood banking purposes the Government of India in the Ministry of Finance should, at the earliest, be approached by the Ministry of Health to secure special dispensation under Section 35 of the Income-tax Act, making it possible to grant exemption of 100 per cent basis to the donations given to registered and authorised National Council and State Councils. The fulfilment of this objective should be specifically reported by the Ministry of Health to the Hon'ble Supreme Court. The National Council and State Councils should also utilise opportunities which may be available for securing financial sanction and other support to their blood banking programmes from International sources and other donor agencies.

iii) The Ministry of Health should follow up the recommendations made by the Expert Committee set up by the Indian Red Cross Society to start M.D. Course in blood transfusion technology, and to also undertake the preparation of comprehensive programme for training of personnel operating in relation to various aspects of functioning of blood banks, storage of blood, fractionalisation of blood, and transfusion of blood.

iv) The system of licensing of blood banks will be strengthened to ensure that all quality banks operating in the country are equipped with licenses within a period of not more than one year. Where any blood banks remain ill-equipped for being licensed, and remain unlicensed after the expiry of the period of one year, their

operations should be rendered impossible through suitable action under appropriate legislation. It shall be a policy objective of the Ministry of Health as well as the National Council and the State Councils established on the basis of these recommendations that the prevalent system of professional donors is discouraged through utilisation of all appropriate media, through withdrawal of licences where any such blood bank has been licensed, and by launching prosecutions under the appropriate provisions of law. The objective of total elimination professional donors should be achieved in a period of not more than two years through utilisation of all requisite measures. For attainment of objectives and programmes of the local organisation, the State Govt. will be approached for providing the requisite inspectorate for continuing inspection of blood banks."

11. The Committee has taken note of the programme for preventing infection and strengthening of Blood Banking system in the country that is being implemented by the National Aids Control Organisation, which is annexed as Annexure-I to the report of the Committee.

12. The Indian Association of Blood Banks has been impleaded as party in these proceedings and an affidavit of Dr. V. B. Lal, President of the said association has been filed.

13. We have heard Shri H. D. Shourie, the petitioner in person. Shri A. S. Nambiar, the learned Senior Counsel for the Union of India, Shri P.P. Rao, learned Senior Counsel for the Indian Association of Blood Banks, Dr. V. Gauri Shankar, learned Senior Counsel for the Indian Red Cross Society and the learned counsel appearing for the States. Keeping in view the report of the committee that has been constituted by this Court and the report of the committee of experts set up by the Indian Red Cross Society and the programme that is being implemented by the National Aids Control Organisation as well as the submissions of the learned counsel, we are of the view that suitable action should be taken by the Union Government as well as the Government of the States and the Union Territories Administration in accordance with the plan for immediate implementation as well as the plan for long implementation suggested by the committee constituted by this Court.

14. It no doubt true that after the report of M / s. A. F. Ferguson & Co. the Union Government has taken certain steps towards improving the state of affairs regarding the blood banks in the country and the National Aids Control Orgainsation is also working in this field. But a lot more is required to be done as would be evident from the reports of the Committee constituted by this Court and the Committee of Experts appointed by the Indian Red Cross Society. The Committee constituted by this Court has made concrete suggestions in this regard. We are in agreement with the recommendations of the said committee that the entire range of schemes related to operation and requirements of blood banks including the launching of effective motivation campaigns for stimulating voluntary blood donations, launching programmes of blood donations, training of personnel in relation to all operations of blood banking should be entrusted to an autonomous representative body at the national level which may be called the National Council on Blood Transfusion, as suggested by the Committee. The National Council would exercise the function entrusted to it in coordination with similar bodies established at State Level which may be called State Councils. In order that they may have their own individuality and funds and are able to raise funds from various sources including of contributions from trade, industry and individuals the National Council and the State Councils should be constituted as societies registered under the Societies Registration Act. The National Council and the State Councils should undertake the measures suggested by the Committee constituted by the Court as well as the Committee of experts appointed by the Indian Red Cross Society and while doing so they coordinate their activities which

those of the National Aids Control Organisation and other agencies in this field. Keeping in view the potentialities of the harm in the prevailing state of affairs and the need for speedy action in this regard, we consider it appropriate to give the following directions.

1. The Union Government shall take steps to establish forthwith a National Council of Blood Transfusion as a society registered under the Societies Registration Act. It would be a representative body having in it representation from the Directorate General of Health Services of the Government of India, the Drug Controller of India, Ministry of Finance in the Government of India, Indian Red Cross Society, private blood banks including the Indian Association of the Blood Banks, major medical and health institutions of the country and non-government organisation active in the field of securing voluntary blood donations. In order to ensure coordination with the activities of the National Aids Control Organisation, the Additional Secretary in the Ministry of Health, who is in charge of the operations of the programme of National Aids Control Organisation for strengthening the blood banking system could be the president of the National Council.
2. The National Council shall have a secretariat at Delhi under the charge of a Director.
3. The basic requirements of the funds for the functioning of the National Council shall be provided by the Government of India but the National Council shall be empowered to raise funds from various other sources including contributions from trade, industry and individuals.
4. In consultation with the National Council, the State Government. / Union Territory Administration, shall establish a State Council in each State / Union Territory which shall be registered as society under the Societies Registration Act. The State Council should be a representative body having in it representation from Directorate of Health Services in the State, State Drug Controller, Department of Finance of the State Government / Union Territory Administration, important medical institutions in the State / Union Territory. Indian Red Cross Society, private blood banks, Non-Governmental Organizations active in the field of securing voluntary blood donations The Secretary to the Government in charge of the Department of Health could be the President of the State Council.
5. The State Council should have its headquarters at the premises of the premier medical institution or hospital in the State / Union Territory and should function under the charge of a Director.
6. The funds for the State Council shall be provided by the Union of India as well as the State Government / Union Territory Administration. The State Council shall also be empowered to collect funds in shape of contributions from trade, industry and individuals.
7. The programmes and activities of the National Council and the State Councils shall cover the entire range of services related to operation and requirements of blood banks including the launching of effective motivation campaigns through utilisation of all media for stimulating voluntary blood donations, launching programmes of

blood donation in educational institutions, among the about industry and trade, establishments and orgainsations of various services including civic bodies, training of personnel in relation to all operations of blood collection, storage and utilisation, separation of blood groups, proper labelling, proper storage and transport, quality control and archiving system, cross-matching of blood between donors and recipients separation and storage of components of blood, and all the basic essentials of the operations of blood banking.

8. The National Council shall undertake training programmes for training of technical personnel in various fields connected with the operation blood banks.

9. The National Council shall establish an institution for conducting research in collection, processing, storage, distribution and transfusion of whole human blood and human blood components, manufacture of blood products and other allied fields.

10. The National Council shall take steps for starting special post-graduate courses in blood collection, processing, storage and transfusion and allied fields in various medical colleges and institutions in the country.

11. In order to facilitate the collection of funds for the National Council and the State Councils, the Government of India (Ministry of Health and Ministry of Finance) should find out ways and means to secure grant of 100% exemption from income-tax to the donor in respect of donations made to the National Council and the State Councils.

12. The Union Government and the Government of the States and Union Territories should ensure that within a period of not more than one year all blood banks operating in the country are duly licensed and if a blood bank is found ill equipped for being licensed, and remains unlicensed after the expiry of the period of one year, its operations should be rendered impossible through suitable legal action.

13. The Union Government and the Governments of the States and Union Territories shall take steps to discourage the prevalent system of professional donors so that the system of professional donors is completely eliminated within a period of not more than two years.

14. The existing machinery for the enforcement of the provisions of the Act and the Rules should be strengthened and suitable action be taken in that regard on the basis of the Scheme submitted by the Drugs Controller (I) to the Union Government for upgradation of the Drugs Control Organisation in the Centre and the States (Annexure II to the affidavit of Shri R. Narayahawami, Assistant Drug Controller, dated September 16, 1994).

15. Necessary steps be taken to ensure that Drugs Inspectors duly trained in blood banking operations are posted in adequate numbers so as to ensure periodical checking of the operations of the blood banks throughout the Country.

16. The Union Government should consider the advisability of enacting a separate legislation for regulating the collection, processing, storage, distribution and transportation of blood and the operation of the blood banks in the country.

17. The Director General of Health Services in the Government of India, Ministry of Health shall submit a report by July 15, 1996 about the action taken in pursuance of these directions.

18. It will be open to the Director General of Health Services, Government of India as well as the National Council to seek clarification / modification of the these directions or further directions in this matter.

15. The writ petition is disposed with these directions. No order as to costs.

Order accordingly.