

2015 (1) DrugsCases(DC) 380

GUJARAT HIGH COURT

Hon'ble Judges:A.J.Desai, J.

Prathama Blood Centre Versus State Of Gujarat

Special Civil Application No. 15119 of 2013 ; *J.Date :- APRIL 11, 2014

- [CONSTITUTION OF INDIA](#) Article - [226](#), [14](#), [19\(1\)\(g\)](#)
- DRUGS AND COSMETICS RULES, 1945

Cases Referred to :

1. Common Cause V/s. Union Of India, AIR 1996 SC 929

Equivalent Citation(s):

2015 (1) DrugsCases(DC) 380 : 2014 AIJ_GJ 235245

JUDGMENT :-

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1 Before dealing with the disputes involved in the present petition, certain aspects related to the same are required to be narrated which are as under:

2 The Hon'ble Apex Court took up an issue with regard to functioning of 'Blood Banks established all over India, when a Public Interest Litigation petition was filed before it. Considering the blood an essential component of the body, which provides substance to life and considering the activities of Blood Banks which undertook the task of collecting, testing and storing the whole blood and its components and subsequently make the same available to the patients in India, the Hon'ble Apex Court issued certain interim directions to the Union of India and State Governments. The petition was finally disposed of by issuing certain recommendations, suggestions and directions for revamping system of Blood Banks in the country as well as issued directions to the Union of India, all State Governments and Union Territories. The said decision is reported as Common Cause v. Union of India, as reported at AIR 1996 SC 929.

2.1 Union of India was directed to take appropriate steps to establish a "National Council for Blood Transfusion" (NCBT) as a society to be registered under the Societies Registration Act. It was further directed that the NCBT shall be represented by Directorate General of Health Services, Drugs Controller of India, Ministry of Finance, in the Government, etc. It was further directed that in consultation with NCBT, the State Government/Union Territory Administration shall establish such State Council i.e. State Council of Blood Transfusion (SCBT) in each State/Union Territory and the same shall be registered as a Society under the Societies Registration Act. The SCBT should be a representative body in each State/Union

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Territory having representation from Directorate of Health Services in the State, State Drug Controller, etc.

3 Pursuant to the above decision of the Hon'ble Apex Court, NCBT has been carrying on its activities, like wise, the State Council in each State/Union Territory. There are several provisions under the Drugs and Cosmetics Act, 1940 as well as the Drugs and Cosmetics Rules, 1945 which provides method of establishing a Blood Bank, organising blood camps, how to preserve the blood and its components collected from the people at large, etc. and in what manner the blood can be transfused or to make blood available to the community people in need.

4 Now certain facts of the present case are briefly stated as under:

4.1 The petitioner was granted a licence to operate a Blood Bank for collection, storage and processing of whole human blood and/or its components for sale or distribution on no profit no loss basis under Rule 122G of the Drugs and Cosmetics Rules, 1945, which was issued by the authorities especially under the Food & Drugs Control Administration on 27.9.2000 and certain conditions were imposed on the petitioner while issuing such licence. Initially, licence was granted for one year but has been renewed time and again and last certificate issued by the competent authority is 2.8.2013 by which licence is renewed upto 31.12.2016. In the year 2001, the Gujarat State Council For Blood Transfusion (GSCBT) permitted the petitioner to conduct voluntary blood donation camps on certain conditions which were time and again extended by GSCBT. By communication dated 3.12.2003, the State Council permitted the petitioners Blood Bank to carry out these activities for Ahmedabad (City), Ahmedabad (Rural), Kheda and Surendranagar Districts.

4.2 Certain hospitals of Ahmedabad (City), Ahmedabad (Rural), Anand and Sabarkantha Districts were granted permission to store of human blood or its components so that they can distribute the bloods to the needy people in the surrounding area. The competent authority while issuing certificate to these hospitals, the petitioner was one of the Blood Banks from whom the said hospitals were permitted to procure the blood units for storage.

4.3 In beginning of 2012, GSCBT arranged a meeting of highest officers of various departments of the State of Gujarat related to Food & Drugs Control Administration to discuss change in policy for issuance of No Objection Certificate to conduct outdoor blood donation camps as well as to discuss the territorial limits of Blood Banks which were engaged in the activities related to blood collecting, testing transfusion, storing, etc of the human blood and its components. On 2.3.2013, a public notice was issued by the Director of GSCBT and invited all concerned to make suggestions with regard to the proposed change of policy for issuance of No Objection Certificate to conduct outdoor blood donation camps as well as to discuss the territorial limits of Blood Banks, etc. The same was also published in the Website of GSCBT.

4.4 Subsequent to the said advertisement, on 27.6.2012, meeting of Governing Board of GSCBT was held wherein several Officers of the Government and one representative from Smt. Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai, attended the meeting and, ultimately, certain decisions were taken. A policy

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was framed on 1.8.2012 by GSCBT and the same was issued to all the Blood Banks in the State of Gujarat. In the meeting, it was decided that (i) Blood Bank should conduct camps within the district where the Blood Bank is located, and (ii) for Medical College having IHBT Department, this territorial limits will not be applied.

4.5 On receiving of this Policy dated 1.8.2012, the present petitioner by its communication dated 3.8.2012 requested to the GSCBT to exclude the petitioners from carrying on its activities with regard to only one district since it has expanded its activities pursuant to the permission granted by the GSCBT on 3.12.2003, which is referred to in the earlier part of this order. Similar requests were made on the same line subsequent to its earlier requests.

4.6 On 16.4.2013, the petitioner Blood Bank was served with a Notice dated 16.4.2013 calling upon the petitioners that why an action should not be taken against the Blood Bank for not obeying the Policy dated 1.8.2012 issued by the GSCBT. A detailed reply was given by the petitioners explaining the circumstances in which the petitioners had carried out the activities other than the District where they were restricted its activities granted by the Government in the year 2003. GSCBT after hearing the petitioners and considering several aspects of the matter, passed an order on 31.8.2012 by which the Council withdrew the permission granted to the petitioners to conduct the outdoor blood donation camps, Regional Blood Transfusion Centers came to be withdrawn and a recommendation was made to the Food & Drugs Control Administration to cancel/suspend the approval of all the Blood Storage Centers of the petitioner Blood Bank.

4.7 Being aggrieved and dissatisfied with the said order and with the Policy dated 1.8.2012, the petitioner has filed the present petition under Articles 14, 19(1)(g) and 226 of the Constitution and has challenged the Policy as well as the Order dated 31.8.2013 passed by the respondent No.3 - Gujarat State Blood Transfusion Council.

5 Mr. K.S. Nanavati, learned Senior Counsel assisted by Mr. Nandish Chudgar, learned Advocate for the petitioners has raised the following main grounds, among others.

(i) GSCBT is not empowered to issue such policy, which is contrary to the provisions of the Drugs & Cosmetics Act and Rules, which restricts the activities of a Blood Bank within a particular territorial limit. Licence to establish the Blood Bank is issued by a competent authority, under the provisions of Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, which can impose such restrictions and not to cancel the licence which is working as per the guidelines issued by the NCBT.

(ii) NCBT has not imposed such limitation to any such Blood Bank or restricted the activities which are being carried out by the Blood Bank, otherwise, in accordance with the Act and Rules. By taking me through a Communication dated 11.12.2013 issued by the Ministry of Health and Family Welfare, Department of AIDS Control, Government of India, Mr. Nanavati, learned Senior Counsel, would submit that the Ministry has made clear that as per the national blood policy, no territorial limit has been imposed for blood collection in Gujarat and, therefore, the Policy dated 1.8.2013 issued by the Gujarat State Council for Blood Transfusion is required to be set aside.

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(iii) The order impugned has been passed on extraneous consideration. The petitioner was never called upon to reply or to explain certain factual aspects with regard to an incident, which is relied by Council in passing the impugned order.

6 On the other hand, Mr. P.K. Jani, learned GP, assisted by Ms. Krina P. Calla, appearing for the respondents No. 1 and 3 has vehemently opposed this petition and submitted that, though, all the Blood Banks were invited to discuss this issue involved, the present petitioner - Blood Bank did not participate in the discussion and has come forward by way of the present petition at a belated stage, that too, only when an adverse order has been passed against it. He would further submit that the State Council itself had permitted the petitioners to take up the activities for Ahmedabad (City), Ahmedabad (Rural), Kheda and Surendranagar Districts, which was accepted by the petitioner in the year 2003 and when the GSCBT intends to modify its policy, the petitioner cannot now raise the contention that the State Council has no authority to issue such policy. By taking me through the affidavit-in-reply, Mr. Jani, learned GP would submit that modified policy has been laid down by the State Council which is an independent authority and, that too, after detail discussion amongst all the members with regard to the blood transfusion activities and, therefore, this Court would not like to interfere with the policy framed by the State Council. He would submit that at present there are about 138 such Blood Banks in the State of Gujarat which carry out activities like the petitioner one. It is the case of the State Council that for better quality of blood and its preservation, such territorial restriction is necessary. Mr. Jani, learned GP, would further submit that during the course of hearing of the proceedings, certain irregularities were found against the petitioners and, therefore, some more details have been referred to in the order and, therefore, it cannot be said that the authority has travelled beyond the scope of notice. By taking me through the interim order dated 30.11.2013 passed by the Division Bench of this Court in Writ Petition (PIL) No. 159 of 2011 Mr. Jani, learned GP, would submit that certain directions have been issued by the Hon'ble Division Bench to all the Blood Banks in the State of Gujarat with regard to their activities and it has been directed to the State Government to constitute a Committee for various purposes. He would further submit that the petitioners have not followed the policy issued by the State Council and the petitioners have organised certain blood camps outside the district and has committed breach of policy and, therefore, the order impugned is passed in accordance with law which does not require any interference.

7 Considering the above aspects of the matter, the following aspects are required to be gone into details:

(i) The powers of the State Council to modify policy by which the activities of a Blood Bank has been ordered to be restricted within the territorial limit in which it is established, since National Council has not issued such guidelines and when a specific information has been provided by National Council that as per the national blood policy, no territorial restriction has been imposed for blood collection in Gujarat.

(ii) Whether the State Council can impose conditions other than which are provided under the Drugs Act and Rules, though, National Council and State Councils have been established as per the judgment of the Hon'ble Apex Court in the case of Common Cause v. Union of India (supra).

(iii) The petitioner was called upon by the State Council to respond with regard to the activities carried by it beyond the territorial jurisdiction as per the policy dated 1.8.2012. However, the order impugned in the petition has been passed relying upon

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the other materials which were placed before it and the same are reflected in para18, 19 and 20 of the Order impugned dated 31.8.2013. Therefore, the State Council has decided the case de hors the contents of the notice or not.

8 Hence, Rule returnable on 4.08.2014. Mr. P.K. Jani, learned GP waives service on behalf of respondents No.1 and 3.

9 As far as interim relief is concerned, I have considered the submissions made by Mr. K.S. Nanavati, learned Senior Counsel, for the petitioners as well as the alternative submission made and referred to herein-above that the petitioners may be permitted to continue its activities with regard to blood transfusion, arranging camps within the territorial limits of Ahmedabad City, etc. till the petition is finally heard.

9.1 Without going into the details with regard to the merits and demerits of the case, I am of the opinion that considering the decision of the Apex Court in the case Common Cause v. Union of India (supra) and particularly the observations made in para14 of the said judgment, which empowers the National Council to control the activities of the Blood Banks in the entire country and when the State Council has to act in consultation with the National Council, I am of the opinion that the National Council is the supreme authority/body as far as controlling the Blood Banks are concerned. Therefore, when there is no policy with regard to the territorial restriction of blood transfusion activities, the present petitioner-Blood Bank cannot be debarred from carrying on activities in other districts, which was granted way back in the year 2003.

9.2 It is true that in all there are 138 Blood Banks in the entire State of Gujarat and each district has different numbers of such Blood Banks. The activities carried out by the petitioner Bank, even otherwise, in accordance with law, cannot be restricted only on that ground that other Banks are carrying on similar activities in other parts of the State. I am not satisfied with the explanation tendered by the State Council for restriction on such activities in paragraph 34 and 35 of the affidavit-in-reply since the State Council itself has permitted other medical colleges having IHBT Department to carry on its activities beyond the territorial limit and when it is not the case that the petitioner Bank is not fully equipped like other medical colleges having IHBT Department.

9.3 Even otherwise, when the petitioners have prayed that the activities shall be restricted within the territorial limit of Ahmedabad District, I am of the opinion that the following order can be passed as far as interim relief is concerned.

10 The operation and implementation of the impugned Order dated 31.8.2013 passed by the Gujarat State Council is hereby stayed on the following terms:

(i) the petitioners shall carry on its activities within the territorial jurisdiction of Ahmedabad District as per the terms and conditions of the licence issued by the competent authority;

(ii) no large scale blood donation camps shall be organised by the petitioners. As and when regular blood camps are organised by the petitioners, the State Council shall be informed in advance, at least, before seven days from the date of such camp;

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(iii) it would be open for the State Council to take appropriate steps in accordance with law if it is found that the petitioners have committed breach of Drugs and Cosmetics Act, 1940 as well as the Drugs and Cosmetics Rules, 1945; and

(iv) the respondent authority is entitled to take steps if some directions are issued in future by the Division Bench in Writ Petition (PIL) No. 159 of 2011.

(A.J. Desai, J.) Date: 11.3.2014 Today after pronouncement of the order, Mr. P.K. Jani, learned Government Pleader, appearing for the respondents 1 and 3, has requested to suspend the order for some time. Mr. Nandish Chudgar, learned Advocate, for the petitioners has opposed the said request made by learned Government Pleader. I have heard the learned Advocates appearing for the respective parties. On 10.10.2013, a Coordinate Bench of this Court has passed the following order:

"Issue notice returnable on 23.10.2013. Direct Service is permitted. In the meanwhile, it will be open for the petitioners to request the competent authority for permission to carry out activities within the local limits of the revenue District."

It is the case of the petitioners that subsequent to the passing of the above referred order, the petitioners made requests to the respondents authorities to carry out activities within the local limits of the revenue District. However, the same is not responded by the respondents - authorities till today. Considering this aspect, the requests made by Mr. P.K. Jani, learned Government Pleader to suspend this order is refused. Even otherwise, by putting terms, in my opinion, sufficient restrictions are put by this Court upon the petitioners.

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