

IN THE HIGH COURT OF JUDICATURE AT PATNA

Civil Writ Jurisdiction Case No.4877 of 2016

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Veterans Forum for Transparency in Public Life through its General Secretary namely Wing Commander (Retd.) Bishwanath Prasad Singh, son of late R.N. Singh, R/o PNT Colony No. 2, Dahiyawan, Chapra, Bihar.

.... Petitioner/s

Versus

1. State of Bihar through Secretary, Government of Bihar, Patna.
2. The Chief Secretary, Government of Bihar, Patna.
3. The Principal Secretary, Health Department, Government of Bihar, Patna.
4. The State Drug Control Officer, Health Department, Government of Bihar, Patna.
5. The Union of India through Secretary, Ministry of Health, Government of India.
6. The Secretary, Ministry of Health, Union of India.
7. Secretary, Chemical and Fertilizer, Union of India.
8. All India Drug Manufacture's, 102-B, Poonam Chabers, Dr. A.B. Road, Wori, Mumbai through its Secretary.
9. Indian Medical Association, Indraprastha Estate, New Delhi through its General Secretary.

.... Respondent/s

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Appearance :

For the Petitioner : Mr. Dinu Kumar, Advocate

For the Respondents-State : Mr. P. N. Shahi, A.A.G.-10

For the Respondent-UOI : Mr. S. D. Sanjay, Addl. S.G.
Mr. Anshuman Singh, C.G.C.

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CORAM: HONOURABLE THE ACTING CHIEF JUSTICE

And

HONOURABLE MR. JUSTICE VIKASH JAIN

ORAL JUDGMENT

(Per: HONOURABLE THE ACTING CHIEF JUSTICE)

Date: 16-11-2016

The petitioner in public interest writ application sought directions that 38 medicines, mentioned in table II of paragraph 11 of the writ application, are not safe for patients in terms of communication of the Directorate General of Health Services, office of Drug Controller General (I), New Delhi, dated 15th January, 2013; and

that the State Government should ensure that such drugs are not manufactured or sold in the State.

On the other hand, in the counter affidavit filed on behalf of the respondents, reference is made to the directives dated 1st October, 2012, issued by the Government of India, for cancellation of license to manufacture drug formulation falling under the purview of new drugs, including Fixed Dose Combinations, as defined under Rule 122(E) of the Drugs & Cosmetics Rules, 1945. Reference is made to the subsequent directives on the subject of approval of the safety and efficacy of Fixed Dose Combinations permitted for manufacture and sale in the country without due approval from the office of Drug Controller General of India.

In the supplementary counter affidavit dated 30th August, 2016, reference is made to the directives issued on 15th January, 2013 and 17th of June, 2016 that 294 Fixed Dose Combinations were withdrawn, which were given license without approval of the Drugs Controller General of India. Against the said order, there is a stay obtained by the Manufacturers from Madras High Court, which matter is still pending. Even in Delhi High Court, the action of the Central Government was challenged and the writ petition is pending after stay was granted on 12th of May, 2016.

In the second supplementary counter affidavit dated 21st



September, 2016, it is mentioned that out of 38 Fixed Dose Combination Drugs mentioned in paragraph 11 of the writ application, 14 are such drugs, which have not been banned by the Central Government. The remaining 24 drugs were banned either in the year 2007 or in the year 2016, but the matter is sub-judice either before the Delhi High Court or the Madras High Court.

We have heard learned counsel for the parties and find that no direction can be issued at this stage. It is not the stand of the petitioner that 24 drugs, mentioned in paragraph 11 of the writ application, which have not been banned, are being manufactured in the State of Bihar under a licence given by the State Government. In the absence of manufacturers, if any, of such drugs within the State of Bihar, no direction can be issued to stay the manufacturing of such drugs. The parties are at variance whether remaining 24 drugs are part of 294 Fixed Dose Combinations as well as another set of drugs banned on 10th of March, 2016, which is subject matter of challenge before the Madras and/or Delhi High Court, are being sold in Bihar.

The fact remains that it is not the case of the petitioner that the manufacturers of such drugs are manufacturing drugs in the State of Bihar. In any case, the issue of prohibition of manufacturing of Fixed Dose Combinations in respect of the drugs in question is pending either before the Delhi or Madras High Court, which judgment

would be relevant to determine as to whether such drugs can be permitted to be sold within the State of Bihar.

Since complete facts are not on record, we refrain ourselves from passing any order, but grant liberty to the petitioner to file a fresh petition after giving particulars of the manufacturers of 24 drugs within the State of Bihar; or are being sold in the State and also whether such drugs are part of the challenge before the Delhi and/or Madras High Court.

The writ petition stands disposed of.

(Hemant Gupta, ACJ)

(Vikash Jain, J)

Sunil

AFR/NAFR	N. A. F. R.
CAV DATE	N. A.
Uploading Date	19.11.2016
Transmission Date	