T.C.A.No.1058 of 2019

N.KIRUBAKARAN, J.
and
P.VELMURUGAN, J.

(Order of the Court was made by N.KIRUBAKARAN,J.)

"CARTEL OF DOCTORS, PHARMA COMPANIES AND DIAGNOSTIC LABS IS FLEECING THE PATIENTS"

India is a thickly populated country and the population is more than 130 Crores. It is reported that about 50 million patients take treatment from one million doctors in each day in India. The medical facilities available in India are equally compared to foreign countries. Even though foreign patients are coming down to India, especially to Chennai to take treatment, quality medical treatment is not provided to poor and rural people. Indian Pharmaceutical Sector supplies over 50 percent of global demand for various vaccines; 40 percent of generic demand in the U.S and 25 percent of all medicines in U.K. India contributes the second largest share of pharmaceutical and biotech workforce in the world. India's pharmaceutical sector was valued at US$ 33 million in 2017. India's domestic pharmaceutical market turnover is Rs.1,29,015 Crores in 2018, whereas in 2017, it was 1,16,389 Crores.

2.It is complained that drugs are overpriced and unnecessary drugs are being prescribed by a section of medical practitioners at the instance of pharmaceutical companies, apart from prescribing unnecessary tests, scans, X - Rays etc., for commission from diagnostic laboratories. It is being said that Medical Mafia is controlling the pharmaceutical field and they are responsible for overpricing of the drugs. For the purpose of promoting their drugs in the Market, it is being said that the companies are giving incentives such as providing hospitality and foreign trips to the doctors who prescribe their medicines to the patients without considering as to whether it is required or not. A study conducted by support for "Advocacy and Training to Health (SATHI)" states that big pharmaceutical companies bribe doctors through high value bribes such as smart phones, credit cards e-vouchers and even female companionship.

3.The medical companies are said to be overpricing the drugs over and above the maximum sale price fixed by the Government. Thus the patients are compelled to pay more unnecessarily because of overpricing of the drugs or prescription of unnecessary drugs to the patients at the instance of the drug companies. Overpricing of drugs is prohibited by Section 3 of the Drug (Price

Control) Order, 1995. National Pharmaceutical Pricing Authority constituted by the Central Government is the body to implement the provisions of Drug (Price Control) Order, 1995. Though a voluntary code viz., Uniform Code for Pharmaceutical Marketing Practices is in force, the mechanism is stated to be powerless to take action.

4.Taking note of the fact that a section of doctors are receiving gifts, travel facilities, hospitality, cash, monetary grants from the pharmaceutical companies for prescribing their drugs, by virtue of notification dated 14.12.2009, Medical Council of India inserted regulation 6.8.1 in Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 and another clause 6.8.1 (b) on 01.02.2016. The said regulation is usefully extracted hereunder:-

"***6.8.Code of conduct for doctors in their relationship with pharmaceutical and allied health sector industry***"

The Section6.8.1(b) shall be substituted in terms of Notification published on 01.02.2016 in Gazette of India, as under:-

(b) ***Travel Facilities*** *: A medical practitioner shall not accept any travel Facility inside the country or outside, including rail, road, air, ship, cruise tickets, paid vacation, etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME Programme, etc. as a delegate.*

(iii)Action to be taken by the Council for violation of Section 6.8, as amended vide notification dated 10/12/2009, shall be prescribed by further amending the Section 6.8.1 as under:-

SECTION	***ACTION***
6.8.1 In dealing with Pharmaceutical and allied health sector industry, a medical practitioner shall follow and adhere to the stipulations given below:-	
a) ***Gifts****: A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their sales people or representatives.*	***Gifts*** *more than Rs.1,000/-upto Rs.5,000/-: Censure* ***Gifts*** *more than Rs.5,000/-upto Rs.10,000/-: Removal from Indian Medical Register or State Medical Register for 3 10(three) months.* ***Gifts*** *more than Rs.10,000/-to Rs.50,000/-: Removal from Indian Medical Register or State Medical Register for 6(six) months.* ***Gifts*** *more than Rs.50,000/-to Rs.1,00,000/-: Removal from Indian Medical Register or State Medical Register for 1 (one) year.* ***Gifts*** *more than Rs.1,00,000/-: Removal for a period of more than 1 (one) year from Indian Medical Register or State Medical Register*
b) ***Travel facilities****: A medical practitioner shall not accept any travel facility inside the country or outside, including rail, road, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc. as a delegate.*	***Expenses for travel facilities*** *more than Rs.1,000/-upto Rs. 5,000/-: Censure* ***Expenses for travel facilities*** *more than Rs.5,000/-upto Rs. 10,000/-: Removal from Indian Medical Register or State Medical Register for 3 (three) months.* ***Expenses for travel facilities*** *more than Rs.10,000/-to Rs. 50,000/-: Removal from Indian Medical Register or State medical Register for 6 (six) months.* ***Expenses for travel facilities*** *more than more than Rs.50,000/-to Rs. 1,00,000/-: Removal from Indian Medical Register or State Medical Register for 1 (one) year.* ***Expenses for travel facilities*** *more than Rs.1,00,000/-: Removal for a period of more than 1 (one) year*

SECTION	ACTION
	from Indian Medical Register or State Medical Register
c) ***Hospitality****: A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext.*	***Expenses for Hospitality*** *more than Rs.1,000/-upto Rs. 5,000/-: Censure* ***Expenses for Hospitality*** *more than Rs. 5,000/- upto Rs.10,000/-: Removal from Indian Medical Register or State Medical Register for 3 (three) months.* ***Expenses for Hospitality*** *more than Rs.10,000/- to Rs.50,000/-: Removal from Indian Medical Register or State medical Register for 6 (six) months.* ***Expenses for Hospitality*** *more than more than Rs.50,000/-to Rs.1,00,000/: Removal from Indian Medical Register or State Medical Register for 1 (one) year.* ***Expenses for Hospitality*** *more than Rs.1,00,000/-: Removal for a period of more than 1 (one) year from Indian Medical Register or State Medical Register.*
d) ***Cash or monetary grants****:- A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext. Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.*	***Cash or monetary grants*** *more than Rs.1,000/-upto Rs.5,000/-: Censure* ***Cash or monetary grants*** *more than Rs.5,000/-upto Rs.10,000/-: Removal from Indian Medical Register or State Medical Register for 3 (three) months.* ***Cash or monetary grants*** *more than Rs.10,000/-to Rs.50,000/-: Removal from Indian Medical Register or State Medical Register for 6 (six) months.* ***Cash or monetary grants*** *more than more than Rs.50,000/-to Rs.1,00,000/-: Removal from Indian Medical Register or State Medical Register for 1 (one) year.* ***Cash or monetary grants*** *more than Rs.1,00,000/-: Removal for a period of more than 1 (one) year from Indian Medical Register or State Medical Register.*
e) ***Medical Research****: A medical practitioner may carry out, participate in, work in research*	*First time censure, and thereafter removal of name from Indian Medical Register or State Medical*

SECTION	ACTION
projects funded by pharmaceutical and allied healthcare industries. A medical practitioner is obliged to know that the fulfillment of the following items (i) to (vii) will be an imperative for undertaking any research assignment/project funded by industry –for being proper and ethical. Thus, in accepting such a position a medical practitioner shall:- *(i)Ensure that the particular research proposal(s) has the due permission from the competent concerned authorities.* *(ii)Ensure that such a research project(s) has the clearance of national/state/institutional ethics committees/bodies.* *(iii)Ensure that it fulfils all the legal requirements prescribed for medical research.* *(iv)Ensure that the source and amount of funding is publicly disclosed at the beginning itself.* *(v)Ensure that propercare and facilities are provided to human volunteers, if they are necessary for the research project(s).First time censure, and thereafter removal of name from Indian Medical Register or State Medical Register for a period depending upon the violation of the clause.* *(vi)Ensure that undue animal experimentations are not done and when these are necessary they are done in a scientific and a humane way.* *(vii)Ensure that while accepting such an assignment a medical practitioner shall have the freedom to publish the results of the research in the greater interest of the society by inserting such a clause in the MoU or any other documents/agreement for any such assignment.*	*Register for a period depending upon the violation of the clause.*
f) ***Maintaining Professional Autonomy****:- In dealing with pharmaceutical and allied healthcare industry a medical practitioner shall always ensure that there shall never be any compromise*	*First time censure, and thereafter removal of name from Indian Medical Register or State Medical Register.*

SECTION	ACTION
either with his/her own professional autonomy and/or with the autonomy and freedom of the medical institution.	
g) ***Affiliation****:- A medical practitioner may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity. In doing so, a medical practitioner shall always :-(i)Ensure that his professional integrity and freedom are maintained.* *(ii)Ensure that patients interest are not compromised in any way.* *(iii)Ensure that such affiliations are within the law.* *(iv)Ensure that such affiliations/employments are fully transparent and disclosed.*	*First time censure, and thereafter removal of name from Indian Medical Register or State Medical Register for a period depending upon the violation of the clause.*
h) ***Endorsement****:- A medical practitioner shall not endorse any drug or product of the industry publically. Any study conducted on the efficacy or otherwise of such products shall be presented to and/or through appropriate scientific bodies or published in appropriate scientific journals in a proper way.*	*First time censure, and thereafter removal of name from Indian Medical Register or State Medical Register.*

From the above, it is clear that the doctors shall not accept any facilities from the pharmaceutical companies and it is declared to be unethical and action would be taken against the said doctors.

5.Inspite of above regulations, Companies and Doctors are indulging in malpractices. Therefore, there should be an integrated approach to bring down malpractices by Ministry of Health and Family Welfare, Ministry of Pharmaceuticals, National Pharmaceutical Pricing Authority, Medical Council of

India and Income Tax Department by taking appropriate proceedings. The Central Government has to frame statutory "Uniform Code of Pharmaceutical Practices" at the earliest.

6.Here is a case which demonstrates unethical practice of paying doctors and overpricing of drugs by a Pharmaceutical Company. The assessee viz., M/s.Fourrts (India) Labs Pvt Ltd., is a private limited company, engaged in the business of manufacturing Pharmaceutical Formulations. Their products cannot be sold more than the basic price fixed by the Regulatory Authority under Government of India. For the Assessment Year 2012 - 2013, assessee filed their return on 29.09.2012, admitting a total income of Rs.14,69,29,707/-. Subsequently, assessee's case was selected for scrutiny and notice under Section 143 (2) was issued to the assessee. In response to that, assessee's representative appeared and furnished the details required by the Assessment Officer. In the course of assessment proceedings, it was noted by the Assessment Officer that the assessee had claimed deduction for a sum of Rs.5,45,77,209/- as Licences & Taxes and Rs.42,81,986/- towards "Sales Promotion Expenses" including payments to the doctors for promotion of Company's brands of medicine.

7.However, it was found that in the relevant previous year, National Pharmaceutical Pricing Authority [NPPA] had ordered the assessee to refund the excess amount collected by overcharging of prices higher than those fixed or notified by the Government. Further for overcharging amount, interest @ 15% per annum was also levied under Section 7A of Essential Commodities Act. It was contended by the assessee that these payments were nothing but refund of excess amount collected by them and cannot be considered as penalty. The Assessment Officer did not accept the assessee's contention and disallowed the payment made to NPPA on the ground that this amount was paid by the assessee for violating the provisions of Central Act and the same is penal in nature. Thus additions were made and assessment was completed.

8.Aggrieved by the assessment order, the respondent/assessee challenged the same before the Commissioner of Income Tax (Appeals) and it was dismissed. Against the order of the Commissioner of Income Tax, an appeal has been preferred by the respondent before the Income Tax Appellate Tribunal. The Tribunal allowed the appeal of the assessee. Aggrieved over the Tribunal's order, the present appeal has been filed by the Income Tax Department.

9.Heard Mr.Karthick Ranganathan, learned Senior Standing Counsel for the appellant.

10.This tax case is admitted on the following substantial questions of law:

"(i)Whether on the facts and in the circumstances of the case and in law, the ITAT was right in deleting the disallowance made under Section 37 (1) of the Act by holding that refund of excess fund collected by the assessee and interest thereon are allowable as revenue expenditure under Section 37 (1) of the Act?

(ii)Whether on the facts and in the circumstances of the case and in law, the ITAT was right in appreciating the fact that the assessee had acted against the larger public interest to gain unauthorised benefit at the cost of consumer, which is violation of the statutory provisions, hence, the excess price paid to NPPA by the assessee is penal in nature?

(iii)Whether on the facts and in the circumstances of the case and in law, the ITAT was right in not appreciating the fact that the selling of drugs and pharmaceuticals at price higher than the ceiling fixed by NPPA is prohibited by law (Section 3 of DPCO 1995) and clearly falls within the ambit of explanation to Section 37 (1) of the Act?

(iv)Whether on the facts and in the circumstances of the case and in law, the ITAT was right in appreciating the fact that interest payment

for the overcharged amount @ 15% per annum is consequential and is also penal in nature for violation of the statutory provisions?"

11.From the facts mentioned above, it is clear that even though it is prohibited under law, the pharmaceutical companies are still promoting their drugs by providing gifts, travel facilities, hospitality, cash or monetary grant to the doctors to promote their brand medicines. It is also proved that drugs are overpriced illegally by the companies. It is shocking and surprising to note that the company claimed deduction from Income Tax for the amount spent towards sale promotion expenses as well as for licences & Taxes.

12.Though the case on hand is a Tax Case Appeal filed under Section 260A of the Income Tax Act, 1961 this Court suo motu invokes Article 226 to consider the larger issues of bribing of doctors and overpricing of drugs by Pharmaceutical Companies, as they directly affect citizens violating their rights under Article 21 of Constitution of India. This Constitutional Court cannot restrict itself to the issue involved in the appeal and it is duty bound to issue remedial directions to address the above larger issues.

13.Hence, this Court, Suo motu, impleads the

(i).Union of India, represented by its Secretary, Ministry of Health and Family Welfare, New Delhi;

(ii).Union of India, represented by its Secretary, Ministry of Chemicals and Fertilizers, New Delhi;

(iii).National Pharmaceutical Pricing Authority, 3rd/5th Floor, YMCA Cultural Centre Building, No.1, Jaisingh Road, New Delhi;

(iv).Medical Council of India, Pocket - 14, Sector 8, Dwarka, New Delhi - 110077;

as party respondents. Mr.G.Karthikeyan, learned Assistant Solicitor General takes notice on behalf of the respondents 2 to 4 and Mr.V.P.Raman, learned Standing Counsel takes notice on behalf of the 5th respondent.

14.The following queries have to be answered by the newly impleaded respondents:

(i).What is the action taken by the Medical Council India for violation of Regulation 6.8 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 which prohibits medical practitioners from taking any gifts, travel facilities, hospitality, Cash or monetary grant from Pharmaceuticals and allied health sector Industries and also for getting commission from Diagnostic laboratories by prescribing unnecessary tests, scans etc., for the past five years?

(ii).How many medical practitioners have been prosecuted so far, for violation of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 from the year 2009 onwards?

(iii).Who are all the doctors who accepted the hospitality from the respondent company to the tune of Rs.42,81,986/- during the assessment year 2012-13 and what is the action taken against them?

(iv).What are all the other steps taken by the Medical Council of India against the doctors who violate Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 as well as circulars issued by them?

(v).How many pharmaceutical companies have been prosecuted for violating Regulation 3 of the Drug Price Control Order, 1995 for the past five years? [year wise details to be given] (vi).What are all the measures taken by the Government to control the pharmaceutical companies which overprice the drugs in violation of Drug Price Control Order, 1995?

(vii).How many pharmaceutical companies have claimed deduction as for sale promotion expenses to promote their company branded medicine by providing incentives such as gifts, travel facilities, hospitality, Cash or monetary grant to the doctors?

(viii).Whether the Income Tax Department is regularly informing the Central Government and National Pharmaceutical Pricing Authority about the pharmaceutical companies which claim deduction in respect of sale promotional expenses regarding payments and incentives to Doctors and for overpricing of drugs?

(ix).How many complaints have been received so far with regard to overcharging of medicines by National Pricing Authority and other official respondents viz., the Medical Council of India as well as by the Central Government for the past five years? [year wise details to be given] (x).How much was recovered as the amount accrued due to overpricing of drugs from pharmaceutical companies, importer, distributor as per Section 13 of Drug Price Control Order, 1995?

(xi).When a separate "Ministry of Pharma and Medical Devices" as stated by the Hon'ble Union Minister for Chemicals and Fertilizers in February 2018 would be formed?

(xii).When would the Central Government make "Uniform Code of Pharmaceutical Marketing Practices (UCPMP)" statutory as prepared by the Pharmaceutical Department (DoP) to control unethical marketing practices in pharmaceutical industry which is pending consideration by the Government of the past 5 years?

15. Notice to the first respondent returnable by 20.01.2020. Private notice including e-mail, courier and whatsapp is also permitted.

16.Call the matter on 20.01.2020.

(N.K.K.,J.) (P.V.,J.)

06.01.2020