

ITEM NO.102

COURT NO.2

SECTION PIL(W)

S U P R E M E C O U R T O F I N D I A
R E C O R D O F P R O C E E D I N G S

Writ Petition(s) (Civil) No(s). 423/2003

ALL INDIA DRUG ACTION NETWORK AND ORS.

Petitioner(s)

VERSUS

UNION OF INDIA AND ORS.

Respondent(s)

(with appln. (s) for permission to submit additional document(s) and permission to submit additional document(s) and permission to file additional affidavit and directions and amendment of the petition and permission to file additional documents and impleadment and permission to file additional documents and permission to file additional documents and permission to file additional documents)

WITH

W.P. (C) No. 459/2012

Date : 15/07/2015 These petitions were called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE T.S. THAKUR
HON'BLE MR. JUSTICE V. GOPALA GOWDA
HON'BLE MRS. JUSTICE R. BANUMATHI

For Petitioner(s) Mr. Colin Gonsalves, Sr. Adv.
Mr. Divya Jyoti Jaipurkar, Adv.
Ms. Jyoti Mendiratta, Adv.

Petitioner-in-person

For Respondent(s) Ms. Pinky Anand, ASG,
Mr. A.K. Sanghi, Sr. Adv.
Mr. D. S. Mahra, Adv.
Mr. Patharaju, Adv.
Mr. Bharat Singh, Adv.
Mr. R. Rajesh, Adv.

Mr. Jayant Kumar Mehta, Adv.
Mr. Saurabh D. Karan Singh, Adv.

Mr. Shreekant N. Terdal, Adv.

Mr. Bhaskar Bhattachary, Adv.
Mr. Navnit Kumar, Adv.
M/s Corporate Law Group, Adv.

Ms. Shobha, Adv.
Mr. Raghav Pandey, Adv.

UPON hearing the counsel the Court made the following
O R D E R

This petition filed in public interest prays for a series of reliefs set out in paras A to Z of the prayer part of the amended petition.

At the hearing today, Mr. Colin Gonsalves, learned senior counsel appearing for the petitioners, confined his submissions to four major issues which according to him have not been addressed by the Government while formulating and publishing its National Pharmaceutical Pricing Policy, 2012 followed by Drug Price Control Order, 2013. Mr. Gonsalves contended that the Competent Authority has formulated and relied upon a formula that is totally out of tune with the scheme, spirit and object sought to be achieved by the legislation under which the Price Control Order has been issued. In particular, it was contended by Mr. Gonsalves that the formula evolved and applied by the Government for regulating drug prices in the country has not taken note of certain ground realities. For instance the Price Control Order ignores the fact that supplies made by Pharmaceutical companies to the State Governments of drugs covered by the order are made at much lesser rates than those stipulated in the price control order, 2013. The

earlier formula which according to Mr. Gonsalves, took into consideration the manufacturing cost and provided for 100 percent mark-up was a fair method of determining prices of controlled drugs in the country. This formula has been abandoned by the Government to the prejudice of the less fortunate sections of our country who cannot afford even such of the drugs as are acknowledged to be absolutely essential, not only by the World Health Organisation but even by the Government of India. As many as 348 drugs are said to have been included in the list of drugs that are brought under price control in terms of the order mentioned above.

The second limb of Mr. Gonsalves's grievance in the writ petition touches upon the exclusion of certain drugs from the Price Control Order. It is contended by Mr. Gonsalevs that exclusion of life saving drugs/medicines, fix dose combinations and medical preparations belonging to the same chemical class from the Price control Order is wholly unwarranted and unjustified. It was also submitted that the Price Control Order does not extend to dosages and combinations nor does the order cover medicines supplied under the National Health Programme. So also, preparations appropriate for children have not been included nor have medicines needed for major health issues like Diabetes, Hypertension, Tuberculosis, Anemia and HIV been included in the list of drugs. Exclusion of such a large number of drugs which are essential by any standard is according to the learned Counsel wholly unfair and arbitrary.

The third area in which Mr. Gonsalves, made his submissions was about manufacture and sale of large quantities of drugs using irrational combinations. He submitted that the system by which the drugs are certified for human consumption does not appear to be very effective not only because of lack of adequate laboratory and testing facilities but also because of lack of human resources with the agencies who are supposed to subject such drugs to testing process before clearing them for bulk manufacture and use by consumers. He urged that irrational combination of drugs is a major issue not only in terms of such drugs being serious health hazards but also because the Price Control Order does not specifically address the same.

The fourth aspect which Mr. Gonsalves urged before us related to the exclusion of patented drugs from the Price Control order. It is urged that there was no real reason why patented drugs cannot and should not be brought under the price control order issued by the Government.

On behalf of the respondents it was argued by Ms. Pinki Anand learned ASG, Mr. A.K.Sanghi learned senior counsel and other counsel appearing for the remaining respondents that the National Pharmaceutical Pricing Policy, 2012 has been formulated by the Government after due and proper deliberations taking into consideration all relevant aspects including the objective of making drugs affordable for the common man and leaving room for growth of the pharmaceutical companies. It was submitted that the

list of drugs brought under the price control regime was reasonably comprehensive and in tune with the list drawn up by the World Health Organisation. If any drug has been left out of the Price Control Order, the Government can look into the desirability of its inclusion and pass appropriate orders on the subject. It was also contended by learned counsel for the respondents that the formula adopted for fixing of prices of essential drugs is neither anomalous nor opposed to the objects underlying the legislation on the subject. Having said that if the petitioners were to demonstrate by reference to any material available with them any possible absurdity in regard to any specific drug, the Competent Authority would certainly examine the same and take corrective measures. It was urged that although there have been extensive exchange of views between the Competent Authority and the petitioners or their representatives, the Competent Authority would have no objection to re-examine the grievance in case a fresh representation is filed by the petitioners in that regard. Ms. Anand submitted that some of the issues sought to be raised by the petitioners are in fact already under examination at an appropriate level.

In the circumstances and keeping in view the significance of the issues raised before us, we see no reason why the petitioners cannot be permitted to file a fresh representation before the Secretary to the Government of India, Ministry of Chemical and Fertilisers with copies to all concerned pointing out the

deficiencies and anomalies by the petitioners. We make it clear that the petitioners would do well to confine their grievance in any such representation to the four distinct aspects referred to by us hereinabove. Needless to say that upon receipt of the representation from the petitioners, the competent authority shall examine the same, afford the petitioners an opportunity of being heard. It would also consider the material that the petitioners may provide in support of their petitions and the opinion of the experts, if any, on the subject and pass appropriate orders in accordance with law on the subject. The competent authority may while doing so deal with each one of the aspects raised by the petitioners as mentioned above and spell out the reasons in support of the view that it may take on the subject.

The petitioners shall file their representations within six weeks. The competent authority shall examine the the same and communicate its order as early as possible but not later than six months from the date the representation is received. The competent authority shall also place on record with an affidavit the order passed by it before the next date of hearing.

Post these petitions after six months.

(Shashi Sareen)
Court Master

(Veena Khera)
Court Master