IN THE HIGH COURT OF KARNATAKA AT BENGALURU

DATED THIS THE 30TH DAY OF NOVEMBER, 2022

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BEFORE

THE HON'BLE MR. JUSTICE M. NAGAPPASANNA

WRIT PETITION No.11057 OF 2019 (GM – RES)

BETWEEN:

HEALTHCARE GLOBAL ENTERPRISES LIMITED
A COMPANY INCORPORATED UNDER
THE COMPANIES ACT, 1956
HAVING ITS REGISTERED ADDRESS AT
HCG TOWER, NO.8, P.KALINGA RAO ROAD,
SAMPANGI RAMANAGAR,
BENGALURU-27
REPRESENTED HEREIN ITS
AUTHORIZED SIGNATORY
MRS.IPSITA RAAJSHREE.

... PETITIONER

(BY SRI DEEPAK BHASKAR, ADVOCATE)

AND:

1. UNION OF INDIA
THROUGH ITS SECRETARY
DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS AND FERTILIZERS
SHASTRI BHAWAN,
NEW DELHI – 110 001.

2. THE NATIONAL PHARMACEUTICAL PRICING AUTHORITY
THROUGH ITS CHAIRMAN,
HAVING ADDRESS AT 3RD /5TH FLOOR,
YMCA CULTURAL CENTRE BUILDING,

1, JAISINGH ROAD,
NEW DELHI – 110 001.

... RESPONDENTS

(BY SRI M.B.NARGUND, ADDL. SOLICITOR GENERAL FOR
SRI GUTHAM DEV C. ULLAL, CGC)

THIS WRIT PETITION IS FILED UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA PRAYING TO SET ASIDE THE IMPUGNED ORDER DATED 27TH FEBRUARY 2019 VIDE ANNEXURE-A AS ISSUED BY THE RESPONDENTS.

THIS WRIT PETITION HAVING BEEN HEARD AND RESERVED FOR ORDERS ON 15.11.2022, COMING ON FOR PRONOUNCEMENT THIS DAY, THE COURT MADE THE FOLLOWING:-

ORDER

The petitioner, a Healthcare Global Enterprises Limited (hereinafter referred to as 'the Company' for short) is before this Court calling in question order dated 27-02-2019 by which the Ministry of Chemicals and Fertilizers in the Department of Pharmaceuticals imposes a cap on trade margin of 30% and directs manufacturers to fix their retail price based on price at first point of sale of the product of non-scheduled formulations containing in all those 42 drugs listed in the said order.

2. *Shorn* of unnecessary details, facts in brief that are germane for consideration, as borne out from the pleadings, are as follows:

The petitioner claims to be the largest provider of cancer care and is in the forefront of the battle against cancer and claims to have 20 comprehensive cancer care centers across the nation. The petitioner further claims that it has been successfully able to provide innovate and cost-effective methods of treatment and management of cancer. It operates a hub and spoke model and has been acclaimed of both commitment and quality of health care. The petitioner fits into the definition of retailer in any of the enactments that are necessary to be considered in the case at hand. The issue that drives the petitioner to this Court in the subject petition is the order of the Ministry of Chemicals and Fertilizers in the Department of Pharmaceuticals at the National Pharmaceuticals Pricing Authority imposing a cap of 30% upon manufacturers for select anti cancer drugs identified by the Ministry of Health and Family Welfare as being essential for the treatment of cancer invoking its power under the Drugs (Prices Control) Order, the policy to keep the margin to a maximum extent of 30% to the

manufacturers is what is promulgated under the Notification. The petitioner, a retailer who runs cancer care centers and deals with these medicines which are used to combat cancer rushes to this Court once the Notification comes about on 27-02-2019 contending that the petitioner being a stockist, the cap laid on the manufacturer would result in his business getting affected *inter alia.* This Court declined to grant an interim order of stay of any kind of the order impugned but by a detailed order noticed that in the event the petitioner succeeds, his interest would be protected.

3. Heard Sri Deepak Bhaskar, learned counsel appearing for the petitioner and Sri M.B.Nargund, learned Additional Solicitor General of India appearing for the respondents.

4. The learned counsel appearing for the petitioner would contend that the National Pharmaceuticals Pricing Authority who has now issued the Notification is not empowered under the Price Control Order to fix ceiling price or retail price of non-scheduled formulations. The non-scheduled formulations are to be determined

only by the market force and cannot be subject to any regulation. There is no extraordinary circumstance for fixing of ceiling price or retail price of any drug invoking its power under the Price Control Order and, therefore, the cap that is laid at 30% is arbitrary and imposes an unreasonable restriction on the petitioner's right under Article 19(1)(g) of the Constitution of India which depicts right to trade. He would further contend that the Price Control Order is arbitrary, unreasonable and bears no application of mind for capping the trade margin of 42 drugs at 30% and seeks quashment of the order of such capping.

5. On the other hand, the learned Additional Solicitor General of India would vehemently refute the submissions to contend that under the Prices Control Order, the Government is empowered to put a cap on the price of either the manufacturer or the retailer. It is the manufacturer whose price is now capped and not the retailer and the petitioner cannot claim to be an aggrieved person by issuance of the impugned order as it is not the manufacturer. He would contend that for the public good essential drugs can be placed under the price control order as the market forces are

charging 900% over and above the manufacturing cost and the cap is on all the anti-cancer drugs. It is in paramount public interest that it is issued and it was to be in operation for a period of one year and later have to be increased by 10%. Therefore, no manufacturer even can claim that they can continue to impose 900% margin over a cancer drug which is needed to every citizen suffering from such a disease. He would, therefore, seek dismissal of the petition.

6. I have given my anxious consideration to the submissions made by the respective learned counsel and perused the material on record. In furtherance whereof, the only issue that falls for my consideration is:

"Whether the policy of Government of India in the imposition of cap on trade margin of 30% on the manufacturer is arbitrary and unreasonable?"

7. The Government of India in the Ministry of Chemicals and Fertilizers by a notification on 07-12-2012 promulgated National Pharmaceuticals Pricing Policy, 2012. The policy initially comes about in the wake of aftermath of Chinese aggression resulting in

the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. They were all promulgated under the Defence of India Act. Based on this, the National Pharmaceuticals Pricing Policy, 2012 was notified. The objectives of the policy are as found in the said Notification reading as follows:-

> *"2.* ***Objectives of the Present Policy.***
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> *As stated above, in its present form, the Drug Policy of 1994 needs to be modified in the contest of changed global environment for industry as well required changes in the mechanism to make available essential medicines to the masses.* ***The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The reasons are further elaborated later in the Pricing Document."***
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> *(Emphasis supplied)*

The key principles are also enunciated in the said policy. Clause (xii) of the policy which deals with non-price control drugs reads as follows:

> *"(xii)* ***Non-price Control Drugs****: Under the existing price control regime, the prices of Non-Scheduled Drugs are monitored and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, Government fixed the prices of such medicines from time to time. In the*

> *proposed policy, all essential drugs are under price control.* ***It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of about 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months."***
>
> *(Emphasis supplied)*

The objective of the policy was to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharmaceutical industry. The key principle of the policy was regulation of price of drugs on the basis of essentiality of such drugs which would be different from the economic criteria/market share principle hitherto adopted in the drug policies. 'Essentiality' was the key feature.

8. Exercising its powers conferred under the Essential Commodities Act, 1955 and in supersession of the Drugs (Prices Control) Order, 1995, the Government of India notifies the Drugs (Prices Control) Order 2013 (hereinafter referred to as 'the Prices

Control Order' for short). Certain clauses of the Price Control Order are germane to be noticed. Clause 2 deals with definitions. Ceiling price is defined under clause 2(d) and reads as follows:

> *"(d) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of the Order."*

Retail price is dealt with under clause 2(z) and reads as follows:

> *(z) "retail price" means the price fixed by the Government for a new drug under paragraph 5;*

Clause 5 dealing with calculation of retail price of a new drug for existing manufacturers of scheduled formulations reads as follows:-

> *"5. **Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.** – (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph-4.*
>
> *(2)(i) The price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" o the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph-15.*
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> *(ii) The retail price of such new drug shall be fixed by adding sixteen per cent margin to retailer on the price to retailer as fixed in item (i)."*

Clause -7 deals with margin to retailer and it reads as follows:

*"7. **Margin to retailer. –** While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed."*

Clause-10 deals with pricing of the formulations covered under Drugs (Prices Control) Order, 1995, and it reads as follows:

"10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.- *(1) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e, up to 30th May 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations.*

(2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order, 1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.

(3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to the 30th May

2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

(4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non- scheduled formulations as stated in paragraph 20 of this Order."

Clause-19 forms the soul of the Order, dealing with fixation of ceiling price of the drug under certain circumstances and it reads as follows:

"19. Fixation of ceiling price of a drug under certain circumstances: *Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year."*

Clause 20 deals with monitoring the prices of non-scheduled formulations and it reads as follows:

"20. Monitoring the prices of non-scheduled formulations.- *(1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten*

percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty."

9. On a reading of the afore-quoted clauses of the Prices Control Order what would emerge is, the ceiling price which is the price fixed by Government for the scheduled formulations can be regulated. So is the retail price. The power available for such regulation is under clause-19 which begins with a non-obstante clause reading "Notwithstanding anything contained" in this order, the Government may, in extraordinary circumstances, if it considers necessary, to do so in public interest, fix the ceiling price or retail price of any drug for a particular period. The Government is also empowered to vary the price of a drug that is already fixed and notify increase or decrease in the ceiling price or the retail price irrespective of annual wholesale price index for that year. Therefore, the fixation of ceiling price of a drug is a power available notwithstanding anything contained in the Prices Control Order. Clause 20 also permits monitoring of non-scheduled formulations by

Government. Non-scheduled formulations form the subject matter of the present petition. Clause 20 empowers the Government to monitor maximum retail prices of all the drugs including non-scheduled formulations to ensure that no manufacturer increases the maximum retail price of a drug more than what is found in clause 20. Schedule-I to the said order enlists what drugs that would come within the ambit of such control. Based upon the aforesaid policy and the Prices Control Order, the Government of India in the Ministry of Chemicals and Fertilizers notifies the order dated 27-02-2019, the impugned order. Clauses 6, 10 and 15 of the Order read as follows:

> *"6. And whereas, the Authority noted that while the scheduled formulations currently under price cap form 16-17 per* ***cent of the pharma industry, the only control on the remaining*** *non-scheduled drugs is by ensuring that the annual price increase is not more than 10%. The Government has been examining options for rationalisation of prices in this segment in a graded manner.* ***One major factor that contributes to high drug prices in India, is the unreasonably high trade margins. Trade margin is the difference between the price at which the manufacturers sell the drugs to stockiest/distributors (price to stockiest) and the final price to patients (maximum retail price).***"
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> … … … …
>
> *10. And whereas, the Authority noted that 'Cancer is one of the leading causes of adult illness and death due to chronic and non-communicable diseases (NCD) in India. As per WHO*

estimate, there are approximately 18 million cases globally and 1.5 million in India alone. There were 8 lakhs cancer deaths in India in 2018. The number of new cases is estimated to rise to do9uble in India in 2040. The financial burden associated with cancer can force parents and households to acute misery and even insolvency. It is also noted that out of pocket (OOP) expenditure on cancer hospitalization is about 2.5 times of overall average hospitalization expenditure. While catastrophic expenditure on cancer inpatient treatment is highest among all NCDs, poor health financing mechanisms and heavy reliance on out of pocket healthcare payments compels several cancer patients to resort to distressed means for treatment financing. In fact, some studies on India suggest that about 60 and 32 percent households resort to borrowings and contributions (from friends and relatives) respectively for cancer hospitalization. It is estimated that almost more than 50% cancer patients avail the private sector facilities and out of pocket expenses in the Health care including cancer care is about around 65%."

… … …

15. ***And whereas, invoking paragraph 19 of DPCO, 2013, the Government hereby puts a cap on trade margin of 30% and directs manufacturers to fix their retail price based on price at first point of sale of product (hereinafter referred as Price to Stockist), as formulated in Table-A, of the non-scheduled formulations containing any of the 42 drugs listed in Table B (whether individual or in combination irrespective of dosage strength, dosage form and/or route of administration."***

(Emphasis supplied)

The order notices the authority i.e., Pharmaceuticals Pricing Authority and the scheduled formulations are under the price cap of 16-17 per cent in the Pharma industry. The only control on the remaining non-scheduled drugs is by ensuring that the annual price increase is not more than 10%. Seeking to rationalize prices in that segment in a graded manner, the order is promulgated as high drug

prices in India were unreasonable. The trade margin was the difference between the price on which the manufacturer sells drugs to stockists and the final price when it reaches the patients. Clause 10 supra notices that cancer is one of the leading causes of adult illness in India and then imposes a price cap on the trade margin of 30% to the manufacturer in terms of clause 15. How the amount would work out is also found in Table-A appended to the Government order and the names of drugs are given therein. The drugs are 42 in number, all of them are drugs that are meant to be treated for patients suffering from cancer. They are **anti-cancer drugs**. Clause (m) of the said order directs that the price so fixed shall be valid for one year from the date of notification and any violation of the Order was to be brought to the notice of the Authority as they were all cancer drugs supplied to hospitals and were required monitoring of maximum retail prices of such formulation.

10. The foundation to the afore-quoted regulatory measures taken by Government lies in a resolution notified on 29-08-1997 by the Ministry of Chemicals and Fertilizers by establishing an

independent body called the National Pharmaceutical Pricing Authority. The resolution reads as follows:

"MINISTRY OF CHEMICALS AND FERTILIZERS
(Department of Chemicals and Petrochemicals)
RESOLUTION
New Delhi, the 29th August, 1997

F.No.33/7/97-PI-1.- Whereas the prices of bulk drugs and the formulations included in the Scheduled categories are being fixed by the Government of India as per the Drugs (Prices Control) Order, issued from time to time under the provisions of Section 3 of the Essential Commodities Act, 1955 (10 of 1955) and the Government have been experiencing that the present mechanism for the fixation and revision of prices of bulk drugs and formulations is cumbersome, complicated and time consuming.

2. And whereas, after careful consideration, the Government is of the opinion that to streamline and simplify the procedure and to bring about a greater degree of transparency as well as objectivity, as expert body should be constituent with the powers, inter alia, to fix prices and notify the changes therein, if any, ofd bulk drugs and formulations, from time to time, under the Drugs (Prices Control) Order;

3. Therefore, the Government have now decided to establish an independent body of experts to be called as the National Pharmaceutical Pricing Authority, consisting of a Chairperson in the status of the Secretary to the Government of India, Members having expertise in the field of pharmaceuticals, economics and cost accountancy and Member Secretary in the status of Joint Secretary/ Additional Secretary to the Government of India, and the same is entrusted with the task of price-fixation revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of the established criteria/guidelines. The National Pharmaceutical Pricing Authority shall be empowered to take final decisions,

> ***which shall be subject to review by the Central Government as and when considered necessary.*** *The Authority shall also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Prices Control) Order. In addition to the above mentioned functions, the Authority is entrusted with certain other functions as detailed in the Schedule annexed to the Resolution."*
>
> *(Emphasis supplied)*

The National Pharmaceutical Pricing Authority was to monitor the prices of de-controlled drugs and oversee the implementation of the Drugs (Prices Control) Order which was then existing. The other functions of the Authority are as found in the Schedule which read as follows:

> ***"SCHEDULE***
> ***Other functions of the National Pharmaceutical Pricing Authority***
>
> *(1) To implement and enforce the provisions of the Drugs (Price Control) Order in accordance with the powers delegated to it;*
> *(2) To deal with all legal matters arising out the decisions of the Authority.*
> *(3) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps;*
> *(4) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations;*
> *(5) To undertake and/or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals;*
> *(6) To recruit/appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;*
> *(7) To render advice to the Central Government on changes/revisions in the drug policy;*

(8) To render assistance to the Central Government in the parliamentary matters relating to the drug pricing."

11. On a coalesce of the afore-quoted regulatory orders notified by Government of India what would unmistakably emerge is that Government of India is empowered to promulgate a pricing policy and regulate prices of certain drugs which are even of non-formulation as formulated drugs are already in the Schedule to the Order. Non-formulated drug is what is sought to be controlled now. The key feature of the policy as noted hereinabove is 'essentiality'. Therefore, the drugs that are sought to be controlled are essential drugs, essential for combating cancer. The reasons for promulgation of the said policy are found in the Notification itself. The notification records that there were eight lakhs cancer deaths in India in 2018 alone and number of new cases are estimated to be on the rise; 50% of cancer patients avail private sector facilities and out of pocket expenses in the health care including the cancer care is about 65%; one major factor that contributed to high drug prices in India were the unreasonably high trade margins. An expert committee of the Ministry of Health and Family Welfare was constituted to examine the issue of manufacturers selling certain

drugs to the consumers at about 900 per cent more than the regular price of a drug. The High Court of Punjab and Haryana in the case of ***RANBAXY LABORATORY LIMITED V. STATE OF HARYANA*** observed that there was no legal provision in force to save the consumer from naked fleecing of consumers by drug manufacturers. All these factors were looked into and 43 anti cancer medicines were brought under price control. Therefore, it is not a case where the price control policy that comes about is either unreasonable or arbitrary for this Court to entertain a challenge to the said policy that too at the hands of a retailer and not the manufacturer. Even otherwise it is such regulatory policy of keeping of price that is sought to be questioned before this court seeking a judicial review of the said policy. Whether this Court can by way of judicial review obliterate or even tinker with the policy is what needs to be considered.

12. It is the aforesaid regulatory policy of the price that is sought to be questioned before this Court seeking a judicial review of the said policy, in exercise of the jurisdiction of this Court under Article 226 of the Constitution of India. Whether this Court can by

way of judicial review annul or even tinker with the policy, is what is to be considered.

13. The afore-quoted clauses, on the face of them, read as products of policy making, by the Ministry of Chemicals and Fertilizers, in the Department of Pharmaceuticals. They are decisions taken to monitor and regulate the price control of anti-cancer drugs. It is trite, that policy is a system of decision making guided by interest than by principle, the interest in the case at hand is public, as they are all anti cancer drugs which are now sought to be regulated. It cannot be forgotten that the policy is only a course of action to deal with a subject matter. An Authority, statutory or otherwise, is entitled to choose a course of action that it thinks necessary or expedient in public interest. The Courts have always exercised judicial restraint and circumspection over the wisdom of the policies of the Government or statutory authorities, save in circumstances where such policy demonstrates caprice, arbitrariness, unreasonableness or is whimsical, so as to offend the tenets of Article 14 of the Constitution of India. This is the only

parameter that would permit constitutional Courts to tinker with the policy particularly of the kind impugned.

14. Reference being made to the judgment of Frankfurter,J. of the U.S. Supreme Court in the case of ***TROP v. DULLES***[1], becomes apposite. The learned Judge, in his dissenting opinion, has observed as follows:

> ***"All power is, in Madison's phrase, "of an encroaching nature". Judicial Power is not immune against this human weakness. It also must be on guard against encroaching beyond its proper bounds, and not the less so since the only restraint upon it is self-restraint……***
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> *Rigorous observance of the difference between limits of power and wide exercise of power - between questions of authority and questions of prudence - requires the most alert appreciation of this decisive but subtle relationship of two concepts that too easily coalesce. No less does it require a disciplined will to adhere to the difference.* ***It is not easy to stand aloof and allow want of wisdom to prevail to disregard one's own strongly held view of what is wise in the conduct of affairs. But it is not the business of this Court to pronounce policy. It must observe a fastidious regard for limitations on its own power, and this precludes the Court's giving effect to its own notions of what is wise or politic. That self-restraint is of the essence in the observance of the judicial oath, for the Constitution has not authorized the judges to sit in judgment on the wisdom of what Congress and the executive Branch do".***
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> *(Emphasis supplied)*

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[1] ***(1958) 356 US 86***

In yet another view Lord Justice Lawton in ***LAKER AIRWAYS v. DEPARTMENT OF TRADE***[2] has held as follows:

> *"In the United Kingdom aviation policy is determined by ministers within the legal framework set out by Parliament. Judges have nothing to do with either policy-making or the carrying out of policy. Their function is to decide whether a minister has acted within the powers given to him by statute or the common law. If he is declared by a Court, after due process of law, to have acted outside his powers, he must stop doing what he has done until such time as parliament gives him the powers he wants.* ***In a case such as this I regard myself, as a referee. I can blow my judicial whistle when the ball goes out of play; but when the game restarts I must neither take part in it nor tell the players how to play".***
>
> *(Emphasis supplied)*

The afore-quoted observations of those learned Judges have been reiterated in plethora of judgments by the Apex Court. In terms of what is laid down in the afore-quoted judgments, what would unmistakably emerge is, for a Judge in terms of his inputs cannot assume the role of a supreme adviser to the administration on policies governing innumerable activities of the State, particularly in today's context of over-expanding horizons which come into the ken of such policy making. By taking oath of office as a Judge, an ordinary man turns himself into a man with a magic wand and qualifies himself to be an unquestionable authority, to advice on

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[2] ***(1977)2 ALL ER 182***

such policies, is inconceivable. It is further trite that the Court would not sit in the arm chair of those experts who have promulgated such policy and overrule them, save in circumstances, as narrated hereinabove.

15. In the case at hand no such circumstance is brought to the notice of this Court by the petitioner for the policy to be termed as arbitrary, whimsical, unreasonable and contrary to any statutory provisions resulting in illegality. All that the petitioner contends is that its right under Article 19(1)(g) of the Constitution of India is taken away. Article 19(1)(g) of the Constitution which gives right to a citizen to practice any profession or to carry on any trade or business cannot be construed to be so absolute, as even the fundamental rights are couched with reasonable restrictions. What the petitioner now seeks to contend by way of a challenge to the Order is that his profit would come down as he is only a retailer; the cap is on the manufacturer but the effect is on the retailer. This cannot be a ground for a judicial review of the impugned policy much less, on the ground that it violates Article 19(1)(g) of the Constitution of India.

16. It is further germane to notice that manufacturers Association had knocked at the doors of the High Court of Bombay calling in question this Prices Control Order of 2013 on the strength of which the present impugned order emanates. The Indian Pharmaceutical Alliance and another had approached the High Court of Bombay in W.P.No.2700 of 2014 calling in question certain notifications on price control of drugs – those enlisted in National List of Essential Medicines, 2011. Clause 19 of the Prices Control Order *(supra)* also fell for consideration before the Division Bench. The Division Bench in ***INDIAN PHARMACEUTICAL ALLIANCE AND ANOTHER v. UNION OF INDIA***[3] holds as follows:

> ***18. It is common ground that the Government has been conferred with the power as afore-noted to be exercised as a part of the duty towards the public. Every power of this nature is, therefore, coupled with a duty, which is to be performed in public interest. That is how an overriding power under para 19 is conferred and to act in extraordinary circumstances and if the Government considers necessary so to do in public interest.***
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> *19. It is not for this court to interfere with the working or functioning of experts in the field. It can be safely concluded that the NPPA is a body of experts. It is guided by para 19 and the DPCO as a whole so also the constitutional mandate indicated above. The power under para 19 and which is discretionary is coupled with a duty. The extraordinary circumstances and the public interest by themselves are guiding*

[3] ***W.P.No.2700 of 2014 decided on 26.09.2016***

factors and even if there are separate guidelines, which may have been issued but now withdrawn, does not mean that there is nothing to guide the exercise of power in terms of this para. Once the aim and object of DPCO is to ensure that essential medicines are made available at affordable prices and the directions of the Hon'ble Supreme Court of India guide the authorities, then, we do not see any substance in the contentions of Ms. Pereira. In any event, the withdrawal of the guidelines is prospective and would not affect the impugned notifications.

20. Though in the affidavit in rejoinder it is urged that there are no extraordinary circumstances and merely because there are some conflicts and internal competition between pharmaceutical companies, para 19 cannot be invoked, as submitted by Ms. Pereira, we do not think that the impugned orders suffer from arbitrariness or total non application of mind. According to the petitioners, no extraordinary circumstances have been indicated. However, we must read each of these orders in their entirety. The orders indicate and in one case in the preamble it is indicated as to how the exercise of power is guided by the above regime. *Secondly, the market failure in respect of the pharmaceutical companies in the context of India can be attributed to several factors, but the main reason is that the demand of medicines is largely prescription driven and a patient has very little choice in this regard. The impugned notifications indicate as to how the NPPA considered the matter in detail. It found that market failure alone may not constitute sufficient grounds for Government's intervention, but when such failure is considered in the context of role the pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing makes medicines un-affordable and beyond the reach of most and also puts huge financial burden in terms of out of pocket expenditure on health care. The guidelines apart, the NPPA considered the matter in detail. It started with inter-brand price variation in respect of single ingredient formulations in eight therapeutic groups, namely, anti-cancer, HIV/AIDS, anti-TB, anti-Malaria, cardiovascular, anti-diabetics, anti-asthmatic and immunological (sera/vaccines) and wherever the MRP of the brands of medicine of a particular formulation exceeds 25% of the simple average price, the same will be capped at the 25%*

level. The notifications indicate as to how there is very high incidence of cardiovascular diseases in the country, which is estimated to affect around 10% of the population and is responsible for 25% of the deaths in the age group of 25 to 69. The affidavits in reply do not supply any additional reasons but are elaborating as to how the said diseases are affecting even the young generation of Indian population. The reasons and which are to be found in the notification itself, therefore, do not suffer from arbitrariness. ***Even if the guidelines stand withdrawn, there are internal checks and balances. They would guide the Government in exercising the discretionary powers in terms of para 19. It is not as if in individual cases these powers cannot be questioned. However, in the facts and circumstances, we are satisfied that in judicial review we should not interfere with the exercise of power by the Central Government. It is not for us to then probe as to whether the circumstances indicated are extraordinary or not. Even otherwise, we are satisfied that they were indeed extraordinary****. Given the increasing number of patients and suffering from afore-noted diseases, we do not think that the Government has exceeded its power or was not justified in exercising it.* ***It has been indicated with sufficient clarity in the affidavits placed on record that the member companies/ manufacturers have not filed their individual grievances nor have they filed individual petitions. Some of the members have accepted the notifications, which are impugned, by filing their price lists. In such circumstances, if the intent is that essential and life saving medicines ought to be available to all, then, all the more we are not in agreement with Mr. Pereira that the writ petition deserves to succeed. We have found from the affidavits placed before us on behalf of the respondents that by implementation of the price notification, the common man has been benefited. The administration of these drugs and medicines, coupled with lifestyle changes, therefore, go in a long way in reducing the threat to the life of number of patients inflicted by serious diseases.***

21. As a result of the above discussion and without in any manner touching any larger issues, we are of the opinion that the first prayer for striking down the

> ***guidelines does not survive in the light of the withdrawal of the guidelines. As far as the second and third prayers are concerned, we do not think that the impugned notifications are required to be interfered with in our extraordinary, equitable and discretionary jurisdiction under Article 226 of the Constitution of India. We have indicated elaborately our reasons for such non-interference. Hence, for the above reasons, the writ petition fails. It is dismissed."***
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> *(Emphasis supplied)*

The Division Bench holds that the price notification issued is for the benefit of common man and, therefore, no interference was called for with the policy of Government in the price control. The petitioners therein tossed the said order before the Apex Court in S.L.P.No.30089 of 2016 only to be dismissed in limine in terms of its order dated 24-10-2016. Therefore, the challenge akin to what is now made has already been dealt with by the Division Bench of the Bombay High Court against which the Apex Court declined to interfere.

17. Insofar as the judgment relied on by the learned counsel for the petitioner in the case of ***MINISTRY OF CHEMICALS AND FERTILIZERS, GOVERNMENT OF INDIA v. CILPA LIMITED – (2003) 7 SCC 1*** is concerned, there can be no qualm about the principle enunciated by the Apex Court in the aforesaid judgment.

The Apex Court also holds that it is axiomatic that the contents of the policy document cannot be read and interpreted as statutory provisions and further holds that breach of a policy decision by itself is not a ground to invalidate the delegated legislation. The facts obtaining before the Apex Court in Cipla Limited was inclusion of certain bulk drugs in the First Scheduled to the Drugs Price Control Order. Analysing the policy and the role of the Government as a delegate of legislative power the Apex Court summarises the issue at paragraph-9 of the said judgment to hold that while classifying the drugs for the purpose of price control it is not open to the Government to flout or debilitate set norms which it professed to follow in the interest of transparency and objectivity. The facts obtaining in the case at hand are entirely different from what fell for consideration before the Apex Court. Therefore, the said judgment is inapplicable to the facts of the case. The judgment rendered by the High Court of Delhi would not lend any assistance to the petitioner, as the judgment rendered by the High Court of Bombay referred to supra was considering this very price control policy. Therefore, the said judgment would lend complete assistance to the respondent/Union of India. Hence, none of the judgments relied on

by the learned counsel appearing for the petitioner would merit any further consideration for they being not applicable to the facts of the case at hand.

18. The control now made of high trade margin by way of Trade Margin Rationalisation Approach, is towards anti-cancer drugs. Cancer is, in public domain, one of the leading causes of adult illness and death. As per World Health Organization estimate 18 million cases globally and 1.5 million in India, are the fatalities as a result of Cancer. The number of cases is estimated to rise to twice to what it is now, by next 15 years and the expenditure on cancer inpatient treatment is today the highest among non-communicable diseases. Cancer patients in India incur heavy expenditure and cancer drugs need to become somewhat affordable so that whenever a treatment is required, it can be treated at the earliest, to the rich and the poor alike. If such policy is not promulgated, the poor or the middle class which forms a majority of the population of this country, can be seen to be succumbing to the disease due to high prices that the manufacturers project resulting in its unaffordability. Therefore, the challenge to the Government

order by a retailer whose motive *inter alia* is profit and the challenge *inter alia* is loss of profit, cannot be countenanced.

19. For the aforesaid reasons, finding no merit in the petition, it is accordingly dismissed.

Sd/-
JUDGE

bkp
CT:MJ