

**IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION**

WRIT PETITION NO. 2700 OF 2014

Indian Pharmaceutical Alliance	}	
and Anr.	}	Petitioners
versus		
Union of India and Ors.	}	Respondents

Ms. Ethel Pereira with Mr. Aditya N. Raut
i/b. M/s. Desai Desai Carrimjee and
Company for the petitioners.

Mr. Anil C. Singh - Additional Solicitor
General with Dr. G. R. Sharma and Mr. D.
P. Singh for the respondents.

**CORAM :- S. C. DHARMADHIKARI &
B. P. COLABAWALLA, JJ.**

DATED :- SEPTEMBER 26, 2016

P.C. :-

1. By this writ petition under Article 226 of the constitution of India, the petitioners, which is an alliance or association of the pharmaceutical companies, whose names are listed, more particularly at page 45 of the paper book (Annexure 'A'), pray that the Guidelines, which have been issued for fixation/revision of prices of scheduled and non-scheduled formulations dated 29th May, 2014 be declared as ultra vires, illegal, null and void and no action can be taken in pursuance thereof. That also should be declared as such and that is how even the office memorandum dated 14th July, 2014 should be set aside.

2. There is also a prayer for issuance of a writ of prohibition against the respondents, their servants, agents and officers from taking, initiating or maintaining any action against the members of the alliance/Petitioner no. 1 pursuant to these guidelines and further, by a writ of certiorari, upon examining the legality and validity of the orders dated 10th July, 2014 (Annexures 'E-1' to 'E-33'), the same be quashed and set aside.

3. The essential prayer is, therefore, that the guidelines once declared as unconstitutional or null and void or illegal, every consequential action must fall to the ground.

4. The association of pharmaceutical companies registered under the Societies Registration Act, 1860 seeking to represent 20 research based national pharmaceutical companies together with its Secretary General has filed this petition. The Union of India, the Secretary of Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Government of India and the National Pharmaceutical Pricing Authority (hereinafter referred to as the "NPPA") are the respondents.

5. The petition proceeds to state that respondent nos. 1 and 2 exercise powers under the two provisions, namely, the Essential Commodities Act, 1955 and the Drugs (Price Control) Order, 2013 (hereinafter referred to as the "DPCO-2013"). The third

respondent is the pricing authority and it implements the new National Pharmaceutical Pricing Policy, 2012 (hereinafter referred to as the “NPPP-2012”) and the DPCO-2013.

6. On 10th July, 2014, by the impugned orders, the notifications on price control of drugs, namely, those enlisted in the National List of Essential Medicines, 2011 (hereinafter referred to as the “NLEM-2011”) have been extended to the first petitioner's members. They are relating to non-scheduled products. The petitioners state that these 33 notifications affect the members of petitioner no. 1. These impugned notifications/orders have been issued on the basis of the internal guidelines dated 29th May, 2014 and issued by the second respondent. They are on the subject of fixation/revision of price of scheduled or non-scheduled formulation under para 19 of the DPCO-2013.

7. It is common ground that the first respondent, from time to time, issues the price control orders referable to and under the Essential Commodities Act, 1955. This control order fixes prices of certain specified pharmaceutical drugs. The first respondent also issues pharmaceutical pricing policies styled as pricing policies laying down, *inter alia*, parameters for including the drugs/formulation within the ambit of price control. The present NPPP-2012 replaces the earlier Drug Policy of 1994.

8. It is stated that a writ petition was filed in the Hon'ble Supreme Court of India and the Hon'ble Supreme Court of India directed respondent nos. 1 to 3 to formulate a list of essential medicines which should fall within the ambit of price control. That is how the NLEM-2011 was declared. That list defines these essential medicines to mean that those covered by a publication issued by the Ministry of Health and Family Welfare and from time to time included in the first schedule of the order by the Government through notification in the official gazette. Now, the ambit and scope of this policy, namely, the NPPP-2012 encompasses several of these essential medicines and which are defined in the above terms.

9. The preamble to the NPPP-2012 is referred in para 6 of the writ petition and which is to limit itself to the central objective of promulgating the principles for pricing of essential drugs as laid down in NLEM-2011. The relevant paragraphs of this policy are reproduced in para 6 and its copy has been annexed as Annexure 'B'. The claim is that regulation of prices of drugs depends upon the principle of essentiality of the drug concerned. This is different from the economic criteria/market share principle adopted in the Drug Policy of 1994. This criterion of essentiality is met by considering the list of medicines specified in NLEM-

2011 as would be revised from time to time and recently declared by the Ministry of Health and Welfare. Subsequent to the NPPP-2012, the government issued DPCO-2013. The formulations, which were made subject to price control, come in different dosage, strength and delivery mechanisms such as tablets, capsules, soft gel capsules, injectibles, syrups etc. Then, it is contended that the DPCO-2013 also refers to the definition of NLEM. There are certain other definitions, namely, “non-scheduled formulation” and “scheduled formulation”. These expressions are defined in para 2(v) and 2(zb) of the DPCO-2013.

Para 19 of DPCO-2013 reads thus:-

“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”

10. It is submitted that Schedule I to the DPCO-2013 not only specifies the formulations, which are brought under price control but also the dosage, strength and delivery mechanism of the said formulations. Thus, a formulation will be a scheduled formulation if it only contains the exact strength and dosage of the drugs as mentioned in the NLEM-2011. Accordingly, it is only the

scheduled formulations as per the dosage, strength and delivery mechanism which are to be price controlled. However, under para 19 of the DPCO-2013, the respondents are given a power, in extra ordinary circumstances, to fix a price for a non-scheduled formulation for a specified period. Annexure 'C' to the writ petition is a copy of the Schedule I of DPCO-2013.

11. The arguments before us focus only on the understanding of the parties of para 19. For the purpose of this para, the guidelines have been issued and according to the petitioners, they guide the exercise of power in terms of para 19 of the DPCO-2013 so far as they empower fixing of price for non-scheduled formulation for a specific period. Para 2 of the guidelines is referred in para 8 of the writ petition and a copy of the entire guidelines is annexed as Annexure 'D'. The petitioners are, therefore, aggrieved and dissatisfied with the exercise of power by respondent nos. 1 to 3 under para 19 of this DPCO-2013. According to the petitioners, respondent no. 3 has issued 33 notifications/orders all dated 10th July, 2014 and has arbitrarily fixed Maximum Retail Price (MRP) including excise duty and local taxes for anti-diabetic and cardiovascular drugs falling under non-scheduled products. That is impugned.

12. The essential contention before us is, therefore, that the extraordinary circumstances in terms of para 19 are determined by these guidelines. That para 19 opens with a non obstante clause and the Government exercises the discretionary power in cases of extraordinary 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.

13. Ms. Pereira appearing in support of this petition firstly contends that the impugned orders are based on erroneous interpretation of para 19. The para empowers the Government to act only in “extraordinary circumstances” and if it considers it necessary in public interest, it can fix the ceiling price or retail price of any drug for such period as it may deem fit. The extraordinary circumstances must be shown to be existing and they must be clearly reflected in the orders passed by taking recourse to para 19. In the impugned order, no where the extraordinary circumstances giving rise to the issuance of the same are indicated. Secondly, and in any event, for the

Government to exercise the power, the extraordinary circumstances cannot be the alleged huge inter-brand differences in branded generics/ off patent drugs, which are indicative of a severe market failure. Even different brands of the same drug formulation are identical to each other in terms of active ingredient, strength, dosage, route of administration, quality product characteristics and intended use, but vary disproportionately in terms of price. These impugned orders/notifications, on their face, do not indicate the extraordinary circumstances and surely the above cannot be extraordinary circumstances. The inter-brand differences are not extraordinary by any means or market failure.

14. Ms. Pereira has then taken us through the guidelines to submit that though extensive affidavits have been filed in reply and rejoinder, now what emerges from the record and post filing of the writ petition is the latest position and indicated in the affidavit, which has been filed by the Deputy Director in the office of NPPA. It is stated therein that the NPPA, in its meeting (150th Authority Meeting) held on 15th September, 2014 decided that all pending proposals for price fixation under paragraph 19 of DPCO shall remain deferred pending resolution of the entire matter by way of court judgment or statutory directions from the

Government. Later, the said internal guidelines dated 29th May, 2014 have been withdrawn on 22nd September, 2014 with immediate effect. However, this statement is clarified by pointing out that this withdrawal is prospective. Ms. Pereira, therefore, would submit that once the matter is pending before the High Court of Delhi [Writ Petition (Civil) No. 4809 of 2014] at the instance of Organisation of Pharmaceutical Producers of India, then, in the light thereof, by withdrawal of these guidelines, it is conceded that the exercise of power in terms of para 19 is unguided, unbridled, unregulated and uncontrolled. There are no guidelines in the field. In these circumstances, it is submitted by her that this court should proceed to quash and set aside the impugned orders/notifications, particularly for the reasons elaborated by her on merits. She submits that once there are no extraordinary circumstances appearing on the face of these impugned notifications, then, they deserve to be quashed and set aside.

15. With her able assistance, we have perused both, the writ petition and the detailed affidavits filed in reply, rejoinder, the additional affidavits as also the relevant statutory provisions.

16. We have also heard the learned Additional Solicitor General and found from the affidavits in reply, the justification that is

provided by the NPPA that the exercise of the power is neither arbitrary nor unreasonable, unfair or unjust. It does not violate the mandate of Article 14 leave alone Article 19(1)(g) of the Constitution of India.

17. In the affidavit, it has been pointed out as to how the DPCO-2013 was promulgated by the Government of India in exercise of powers under section 3 of the Essential Commodities Act, 1955. The power to frame the order and to issue it is thus not challenged and particularly when it is traceable to essential commodities such as drugs and formulations. It is common ground that drugs and medicines are required for treating several ailments and diseases. A vast majority of our population is suffering from varied and complicated diseases. A large population, whether young or old is suffering from such diseases like diabetes and heart ailments because the current life pattern is complex. Some diseases require regular, continual treatment. After diagnosis, the treatment in the form of preventive and maintenance dose of drugs goes on for long period, in some cases covers the life of the patient. The price of such drugs if not controlled and regulated, that would result in these patients being deprived of the essential drugs and medicines. The treatment is of consumption of drugs, which may be in tablet form or

injectibles. Once the treatment is prolonged and sometimes extends to whole life, then, the availability of essential drugs is the duty of the Government. It is not that the constitutional mandate is served by merely bringing the drugs in market. The drugs and medicines must reach all those who can afford and to those who do not afford. It is to serve larger public interest that the Essential Commodities Act, 1955 empowers issuance of the price control order. That is to control production, supply, distribution, price etc. of essential commodities. Medicines/ formulations are essential commodities and that is how DPCO is framed. From the affidavit filed in reply, it is apparent that the duty towards the public is being performed and that has been impressed upon the authorities by the highest court of the country. Similarly, sections 3 and 5 of the Essential Commodities Act empower the Government, acting through the Ministry of Chemicals and Fertilizers to delegate the powers under the DPCO to the third respondent NPPA. That exercises the powers and discharges the functions of the Central Government. This is done vide Standing Order No. 1394(E) dated 30th May, 2013.

18. It is common ground that the Government has been conferred with the power as aforementioned 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.

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 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 aforementioned 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.

22. At this stage, Ms. Pereira submits that she has instructions to seek continuance of the ad-interim order. According to her, that order has been in force from 1st August, 2014. That restricts the respondents from taking any coercive measures to recover amounts, such as price differences and penalties. That also restrains a drastic action and which may be taken to embarrass the individual members.

23. This request is opposed by Mr. Sharma learned counsel appearing for the respondents contesting the petition.

24. After we have heard the learned counsel sufficiently on this point, we are of the view that the request of Ms. Pereira cannot be granted. Firstly, we have found that the impugned notifications do not suffer from non application of mind nor can be termed as

arbitrary. Secondly, as indicated in the affidavits filed on behalf of respondent nos. 1 to 3, several members of petitioner no. 1 have, in pursuance of the impugned notifications, submitted their price list. The pricing policy is already under implementation. Some drugs essential in treatment of cardiovascular and other serious diseases are now available at affordable prices. Such being the object of the exercise and in absence of a individual company complaining any particular measure as coercive, we do not continue the ad-interim order any more. The request in that behalf is refused.

(B.P.COLABAWALLA, J.)

(S.C.DHARMADHIKARI, J.)