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

WRIT PETITION NO. 2216 OF 2015

M/s. Franco Indian Pharmaceuticals
Pvt. Ltd. & Anr. ... Petitioners
Versus
Union of India & Ors. ... Respondents

WITH
WRIT PETITION NO. 885 OF 2015

Indian Drug Manufactures Association ... Petitioner
Versus
Ministry of Chemicals and Fertilizers & Ors. ... Respondents

WITH
NOTICE OF MOTION NO. 257 OF 2015
IN
WRIT PETITION NO. 885 OF 2015

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Mr. Navroz Seervai, Senior Advocate a/w. Ms. Arti Raghavan and Ms. Tavleen Saini i/by Crawford Bayley & Co. for Petitioners in WP/2216/2015.
Mr. Dheeraj Nair a/w. Mr. Pratik Pawar, Ms. Shanaya Cyrus Irani, Ms. Avni Sharma and Ms. Sanjana Pandey i/by J. Sagar Associates for Petitioner in WP/885/2015.
Mr. M. S. Bhardwaj for Respondents in WP/2216/2015.
Mr. G. R. Sharma (through V.C.) a/w Mr. D. P. Singh for Respondents in WP/885/2015.

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CORAM : MANISH PITALE AND
SHREERAM V. SHIRSAT, JJ.

RESERVED ON : 7th MARCH 2026
PRONOUNCED ON : 10th APRIL 2026

Judgment *(Per Manish Pitale, J.)* :

. The petitioner No.1 in Writ Petition No.2216 of 2015 is an entity engaged in the manufacture, marketing and distribution of

pharmaceutical formulations and petitioner in Writ Petition No. 885 of 2015 is the Indian Drug Manufacturers Association (IDMA), which is a registered association of manufacturers of drugs and pharmaceuticals in India. Both the petitions raise issues pertaining to the interpretation and implementation of the Drugs (Price Control) Order 2013 (hereinafter referred to as 'DPCO 2013' for short). The petitioners contend that the respondent No.3 i.e. the National Pharmaceutical Pricing Authority (NPPA) is wrongly interpreting DPCO 2013 to insist on price ceiling for formulations that do not form part of the first schedule appended to DPCO 2013 and that such insistence is not only arbitrary, but it is in the teeth of various clauses of the DPCO 2013 itself. The petitioner-IDMA in Writ Petition No.885 of 2015 has also challenged communication dated 20.06.2014 issued by respondent No.3-NPPA to the Department of Pharmaceutical, which purports to interpret DPCO 2013, contrary to the interpretation of the respondent No.1 through Ministry of Chemicals and Fertilizers (Department of Pharmaceutical).

2. Since the respondent No.3-NPPA proceeded on the basis that formulations, not specifically mentioned in the first schedule to DPCO 2013, were also amenable to price ceiling, certain claims were being made against manufacturers of pharmaceuticals, drugs and formulations for recovery of allegedly overcharged amounts. In that light, the petitioners in both the petitions pressed for interim relief. In both the petitions, interim relief was granted to

the effect that no coercive steps would be taken by the respondents in pursuance of demand notices issued against such manufacturers of drugs and formulations. The interim relief continued to operate in favour of the petitioners. Upon completion of pleadings, the writ petitions were taken up for final hearing.

3. The respondent-Union of India had been issuing drug price control orders from time to time. On 07.12.2012, the respondent-Union of India through Ministry of Chemicals and Fertilizers, issued a notification, specifying the National Pharmaceutical Pricing Policy 2012. In the said policy, after taking into consideration orders passed by the Supreme Court and considering the recommendations submitted by a committee established by the respondent-Union of India, certain principles for regulation of prices of drugs and formulations were laid down. The key principles were identified as essentiality of drugs, control of prices of formulations only instead of specific bulk drugs and market based pricing. It was specifically laid down that the criteria of essentiality for drugs would be met by considering the list of medicines specified in the National List of Essential Medicines (NLEM), as revised from time to time by the Ministry of Health and Family Welfare of the respondent-Union of India. In this regard, reliance was placed on NLEM of the year 2011, as regards price regulation of formulations only instead of bulk drugs and span of price control was specified on the basis of dosages and

strengths as listed in NLEM 2011. It was further specified that formulations only would be priced by fixing a ceiling price and that manufacturers would be free to fix any price equal to or below the ceiling price.

4. It is in the backdrop of the said policy of 2012 that on 15.05.2013, the DPCO 2013 was notified. In the first schedule appended to DPCO 2013, NLEM 2011 was incorporated, thereby specifying the formulations to which the ceiling prices applied. DPCO 2013 defined crucial terms, such as ceiling price, formulation, schedule, scheduled formulation, non-scheduled formulation, price list and other such expressions to assist in interpretation. DPCO 2013 further laid down the manner in which ceiling prices would be fixed for the scheduled formulations and the manner in which the prices even for the non-scheduled formulations would be monitored. Paragraph 31 of DPCO 2013 provided for a power of review in the Government to consider the grievance of any person, who was aggrieved by notification issued under the DPCO 2013. Paragraph 32 of the same, pertained to non-application of provisions in certain cases. It is to be noted that the first schedule to DPCO 2013 virtually reproduced NLEM 2011 and stated the formulations of various pharmaceutical products and drugs in detail, which were covered under the expression 'scheduled formulation', as per DPCO 2013.

5. The respondent-Union of India through the Ministry of Chemicals and Fertilizers, issued orders from time to time, as per

powers conferred under paragraphs 4, 11 and 14 of DPCO 2013, for including specific formulation and also to specify ceiling price for the same.

6. On 21.06.2013, the said respondent issued one such order under DPCO 2013, specifying the formulation 'Metformin Tablets' of strength 500 mg with the ceiling price of Rs.1.56 per tablet. The petitioner No.1 in Writ Petition No. 2216 of 2015-M/s. Franco Indian Pharmaceuticals Pvt. Ltd., which was manufacturing the said formulation, implemented the same in the light of the said order, for its Metformin 500 mg plain tablet. The said petitioner was also manufacturing 'Glyciphage SR 500 mg tablet' being a specific formulation. It contained the ingredient Metformin, but since the same was not mentioned in the first schedule to DPCO 2013, the said petitioner proceeded on the basis that there was no ceiling price fixed for the same. The petitioners contend that this is based on a correct interpretation of DPCO 2013.

7. It is the case of the petitioners in both the writ petitions that the formulations of plain conventional tablet of Metformin also known by its name of Glyciphage, are based on simple wet granulation manufacturing technology, wherein the drug is released at one go in the gastrointestinal tract. In some patients/consumers, it can lead to side effects like diarrhea and nausea. It is further claimed that a different formulation by sustained release was developed in the case of Metformin and

other drugs entailing a sustained release of the drug over a specific timeline. It is claimed that this is based on a sophisticated technology, which utilizes biphasic polymer matrix diffusion technology. In other words, in sustained release formulation, the drug delivery system is different and the dosage form has a prolonged gastric residence. On this basis, the petitioners contend that unless such Sustained Release Formulation (SR) and/or Controlled Release Formulation (CR) are specifically included in the first schedule appended to DPCO 2013, there is no question of the respondent No.3-NPPA insisting on ceiling price on such SR/CR formulations.

8. In the context of the aforesaid issue, the petitioner in Writ Petition No. 885 of 2015 i.e. the IDMA had approached the respondent-Union of India in August 2013, in pursuance of which interactive meetings were held between the parties for discussing DPCO 2013 and the issues arising therefrom. On 19.08.2013, the petitioner-IDMA through its President sent a letter to the Secretary of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers of respondent-Union of India, recording the issues discussed in the interactive meetings and assurances given by the regulatory authorities, including respondent No.3-NPPA, that no untoward action would be taken against manufacturers. A detailed record note of the discussion was enclosed therewith. The petitioners rely upon the same, particularly on responses of the respondent-Union of India

through the Ministry of Chemicals and Fertilizers, which had issued the DPCO 2013, stating that formulations involving innovations and dosages such as SR/CR etc., would be kept out of price control and if they were inadvertently included, the ceiling price would be reworked.

9. On 19/20.09.2023, the respondent-Union of India through Ministry of Chemicals and Fertilizers, sent a letter to the President of the petitioner-IDMA, specifically clarifying that innovative dosage form of scheduled formulations were opined not to be kept under price control, as per the provisions of the DPCO 2013. It was further recorded that since NLEM 2011 was prepared by the Ministry of Health and Family Welfare, the said Ministry was requested to confirm the said aspect of the matter.

10. On 06.12.2013, the Ministry of Health and Family Welfare of respondent-Union of India, in the context of DPCO 2013, issued an office memorandum, specifically stating that conventional forms of drugs like tablets/capsules/injections, as mentioned in NLEM 2011, would be considered as a part thereof and not dosage forms like modified release forms, dispersible, effervescent, soluble, etc., unless they were specified in non-conventional dosage form in NLEM 2011. According to the petitioners, the said communication from the Ministry of Chemicals and Fertilizers dated 19/20.09.2013 and the office memorandum issued by the Ministry of Health and Family Welfare dated 06.12.2013, sufficiently clarify the interpretation of DPCO

2013 and that therefore, there ought not to have been any confusion in the matter.

11. Yet, members of the petitioner-IDMA started receiving notices, claiming that they had overcharged in respect of formulations that were not even included in the first schedule appended to DPCO 2013. In this backdrop, the petitioner-IDMA filed Writ Petition No. 855 of 2015 before this Court. The petitioners in Writ Petition No. 2216 of 2015 also approached this Court in the light of notice dated 22.01.2014 received from respondent No.3-NPPA, claiming that the said petitioners/ manufacturers were not following prices fixed for specific formulations i.e. Glyciphage SR 500 mg tablet, as the Maximum Retail Price (MRP) was much more than the ceiling price. In response, on 08.03.2014, the petitioner No.1 in Writ Petition No. 2216 of 2015, sent a letter to respondent No.3-NPPA, stating that since Sustained Release (SR) formulation of Glyciphage SR 500 mg tablet was not covered in the first schedule to DPCO 2013, the notice ought not to have been issued. Thereafter, a series of such notices and responses were exchanged, but the respondent No.3-NPPA did not consider the responses of the said petitioner.

12. Eventually, on 04.12.2014, respondent No.3-NPPA issued a show cause notice to the said petitioner-M/s. Franco Indian Pharmaceuticals Pvt. Ltd., alleging that it had overcharged to the extent of about Rs.3,85,69,773/- in respect of the formulation of Glyciphage SR 500 mg tablet, calling upon the said petitioner to

pay the amount along with interest. On 22.04.2014, the said petitioner sent a detailed reply to the same. On 16.01.2015, the respondent No.3-NPPA sent the impugned demand notice dated 16.01.2015, calling upon the said petitioner to deposit the alleged overcharged amount of Rs.7,88,37,886/- along with 15% interest, upto 31.01.2015 with the Government, failing which the matter would be referred to the Collector for recovery of amount as arrears of land revenue, under the Essential Commodities Act, 1955. Aggrieved by the same, the petitioners approached this Court by filing Writ Petition No. 2216 of 2015, wherein this Court, while issuing notice by order dated 24.03.2015, granted interim relief, staying the impugned demand notice. As noted hereinabove, this Court also granted interim direction that no coercive steps would be taken in pursuance of notices issued to members of the petitioner-IDMA in Writ Petition No. 885 of 2015.

13. Thereafter, the pleadings in the writ petitions were completed, while the interim orders continued to operate. The writ petitions were taken up for final hearing.

14. Mr. Seervai, learned senior counsel appearing for the petitioners in Writ Petition No. 2216 of 2015, submitted that the aforesaid policy of 2012 brought about a fundamental change in the principles for regulation of prices of drugs by specifying ceiling price for formulations only, instead of bulk drugs. It was submitted that NLEM 2011 was appended as schedule-I to DPCO 2013 and

the paragraphs of DPCO 2013, specifically defined key terms, such as formulation, scheduled formulation, non-scheduled formulation, schedule, ceiling price, etc. It was submitted that a proper reading of the paragraphs of DPCO 2013 demonstrated that only those formulations specifically included in the first schedule appended to DPCO 2013, were subject to ceiling price. It was submitted that the respondent-Union of India through the Ministry of Chemicals and Fertilizers and Department of Pharmaceuticals, exercised power under DPCO 2013 to issue orders from time to time, to specifically add formulations with ceiling prices. On this basis, it was submitted that unless a specific formulation was included in the first schedule appended to DPCO 2013 or unless it was added by way of an order specifically issued under DPCO 2013, it could not be subjected to ceiling price under DPCO 2013.

15. It was submitted that the aforesaid interpretation of DPCO 2013 was clearly supported by the stand of the parent Ministry of the respondent-Union of India, under which respondent No.3-NPPA functions i.e. the Ministry of Chemicals and Fertilizers, manifested in the communication dated 19/20.09.2013 issued to the President of petitioner-IDMA and office memorandum dated 06.12.2013 issued by the Ministry of Health and Family Welfare of respondent-Union of India. Yet, the respondent No.3-NPPA proceeded to issue show cause notices and demand notices alleging overcharging by the petitioners, despite the fact that the specific

formulation Glyciphage SR 500 mg was neither part of the first schedule appended to DPCO 2013 when it was issued, nor was it added by way of a subsequent order issued by exercising powers under DPCO 2013. On this basis, it was submitted that respondent No.3-NPPA could not have acted in defiance of plain reading of DPCO 2013 and the manner in which the parent Ministry had clarified its interpretation and implementation.

16. It was further submitted that the stand taken before this Court on behalf of the respondents was in the teeth of the DPCO 2013. The learned senior counsel appearing for the petitioners in Writ Petition No. 2216 of 2015 referred to a recent judgment of a Division Bench of this Court in the case of *Pfizer Ltd. & Anr. vs. Union of India & Ors.,* **2025 SCC OnLine Bom 3821**. He submitted that although, the said judgment concerned an explanation appended NLEM 2015, certain observations made in the said judgment could assist this Court in considering the contentions raised on behalf of the petitioners herein.

17. It was submitted that in the said judgment, this Court considered the specific drug delivery systems like Sustained Release (SR) and Controlled Release (CR), other than an ordinary tablet. This Court found that when such a specific drug delivery system, other than the ordinary tablet, was intended to be covered under the NLEM, a specific reference to that particular drug delivery system was made in the NLEM. It was submitted that this Court found the stand of NPPA, to the effect that ordinary tablets

would cover sustained release or extended release or dispersible tablets, was not in consonance with the explanation appended to NLEM 2015.

18. It was submitted that in that context, this Court may consider the aforementioned judgment of this Court in the case of *Pfizer Ltd. & Anr. vs. Union of India & Ors.* (supra), while disposing of these petitions.

19. Mr. Dheeraj Nair, learned counsel appearing for the petitioner-IDMA in Writ Petition No. 885 of 2015, adopted the submissions made by the learned senior counsel appearing for the petitioners in Writ Petition No. 2216 of 2015. He specifically referred to illustrations from the documents annexed to Writ Petition No. 885 of 2015, to contend that whenever the respondent-Union of India through the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, consciously decided to include a formulation under DPCO 2013 for price ceiling, a separate order was issued, specifying the formulation as well as the ceiling price. On this basis, it was submitted that the respondent No.3-NPPA could not insist upon price ceiling even in respect of formulations that were not added in the schedule. The learned counsel for the petitioner in Writ Petition No. 885 of 2015 also relied upon the clarification given by the parent Ministry in respect of DPCO 2013, to contend that the respondent No.3-NPPA was not justified in taking a stand contrary to the same. On this basis, it was submitted that this Court may consider allowing

the writ petition.

20. Mr. Sharma, learned counsel appeared for respondents in Writ Petition No. 885 of 2015 and Mr. Bhardwaj, learned counsel appeared for the respondents in Writ Petition No.2216 of 2015. They submitted that the writ petitions are without any merit and that an unnecessary confusion is sought to be created with regard to the interpretation of DPCO 2013. A plain reading of the same would show that the petitions deserve to be dismissed. It was emphatically submitted that the fundamental principle for pricing under DPCO 2013 was essentiality, in line with the policy of 2012. On this basis, it was submitted that when the schedule did not mention a specific drug delivery system like SR or CR, all forms of drug delivery systems of that medicine stood included in the schedule and where there was a specific mention of drug delivery system in addition to the ordinary tablet, separate ceiling price was applied to the same. On this basis, it was asserted that as per DPCO 2013 when a product prepared from a particular salt was stated in the schedule, a formulation providing for a new drug delivery system would not cease to be a scheduled drug or an essential commodity merely because such new drug delivery system was not specifically mentioned in the schedule.

21. It was further claimed that the purpose of NLEM was relevant for procuring medicines under the public health system i.e. public hospitals and it had no relevance to price control as scheduled under DPCO 2013. It was further submitted that the

petitioners never approached the authorities for prior price approval under DPCO 2013 and they cannot escape the liability of overcharging merely because the specific drug delivery system used by them, was not included in the schedule, so long as the particular salt/drug was mentioned in the schedule to DPCO 2013. It was submitted that a new drug delivery system cannot cease to be essential medicine and that the office memorandum dated 06.12.2013 issued by the Ministry of Health and Family Welfare of the respondent-Union of India, cannot be binding on the respondent No.3-NPPA.

22. The learned counsel for the respondents relied upon judgments of Supreme Court in the cases of *Union of India & Anr. vs. Cynamide India Ltd. & Anr.,* **(1987) 2 SCC 720**, *Glaxosmithkline Pharmaceuticals Limited vs. Union of India & Ors.,* **(2014) 2 SCC 753**, *T.C. Healthcare Private Limited & Anr. vs. Union of India & Anr.,* **(2020) 15 SCC 117** and judgment of this Court in the case of *Indian Pharmaceutical Alliance & Anr. vs. Union of India & Ors.,* **2016 SCC OnLine Bom 11541**.

23. By relying on the said judgments, emphasis was placed on the need to have ceiling price for essential medicines and the role of expert body like the respondent No.3-NPPA in the matter of fixing price of drugs and formulations, which ought not to be interfered with in writ jurisdiction.

24. We have considered the rival submissions in the light of the documents placed on record, particularly DPCO 2013 issued in

the backdrop of the policy of 2012. The respondent-Union of India has been issuing drug control price orders from time to time. Prior to DPCO 2013, the earlier order i.e. DPCO 1995 was in vogue. In the light of the policy of 2012, as per notification dated 07.12.2012 issued by the respondent-Union of India through Ministry of Chemicals and Fertilizers (Department of Pharmaceutical), the key principles for pricing of pharmaceuticals and formulations underwent a change. Apart from essentiality of drugs, the pricing was for control of formulations only, instead bulk drugs. This is a crucial factor in the present case.

25. The contents of DPCO 2013 need to be evaluated and interpreted in the backdrop of the aforesaid policy change manifested in the said policy issued in the year 2012. Subsequently, the said DPCO 2013 was issued under Section 3 of the Essential Commodities Act, 1955. It is crucial to note that DPCO 2013 opens with the words that it has been issued in exercise of powers under Section 3 of the Essential Commodities Act, 1955 and in supersession of DPCO 1995.

26. Paragraph 2 of the DPCO 2013 pertains to definitions and some of the definitions are required to be perused for considering the rival submissions. These are as follows :

> *"(d) **"ceiling price"** means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;*
>
> *(i) **"formulation"** means a medicine processed out of or containing one or more drugs with or without use of any*

pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include – (i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines; (ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

*(j) "**generic version of a medicine**" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name;*

*(v) "**non-scheduled formulation**" means a formulation, the dosage and strengths of which are not specified in the First Schedule;*

*(zb) "**scheduled formulation**" means any formulation, included in the First Schedule whether referred to by generic versions or brand name;*

*(zc) "**schedule**" means a Schedule appended to this Order;"*

27. Paragraph 4 of the DPCO 2013 relates to calculation of ceiling price of a scheduled formulation and it states that the ceiling price of a scheduled formulation of specified strength and dosages, as given under the first schedule, shall be calculated as per the formula specified thereunder. Thus, the first schedule appended to DPCO 2013 assumes great significance. The definition of schedule read with scheduled formulation, shows that a formulation, included in the first schedule, would be subject to ceiling price fixed by the respondent, as per the definition of ceiling price. Non-scheduled formulation clearly means a formulation, the dosage and strength of which are not specified in the first schedule.

28. Paragraph 17 of the DPCO 2013 pertains to amendment of the list of scheduled formulations. It provides for power in the respondent to amend the first schedule, revising the same to add or delete formulations and fixing ceiling prices. Clause 2 of paragraph 17 of DPCO 2013, specifically records that the medicines omitted from the first schedule shall fall under the category of non-scheduled formulations. Paragraph 20 of the DPCO 2013 pertains to monitoring the prices of non-scheduled formulations and it specifies that the respondent-Government shall monitor the MRPs of all drugs, including non-scheduled formulations to ensure that no manufacturer increases the MRP of a drug more than ten percent of the MRP during the preceding twelve months and where the increase is beyond ten percent of MRP, it shall be reduced to the level of ten percent of MRP for the next twelve months. In other words, for the scheduled formulation, included in the first schedule appended to DPCO 2013, the ceiling price would apply and even for non-scheduled formulation, the respondent No.1 would have power under paragraph 20 to regulate the same in the context of MRP.

29. Thus, on a conjoint and plain reading of the expressions ceiling price, formulation, schedule, scheduled formulation and non-scheduled formulation, it becomes clear that ceiling price would apply to the formulations specifically included in the first schedule of DPCO 2013. The documents on record show that the respondent-Union of India through the Ministry of Chemicals and

Fertilizers (Department of Pharmaceutical) exercised powers under paragraphs 4, 11 and 14 of the DPCO 2013, pertaining to calculation of ceiling price of a scheduled formulation, ceiling price or retail price of a pack and fixation of ceiling price of a scheduled formulation respectively, to issue orders for the purpose of adding formulations with ceiling prices to the first schedule of DPCO 2013. This clearly shows that where ceiling prices were applied and fixed for specific formulations, such formulations were added by way of specific orders to that effect issued by the said respondent by exercising powers under paragraphs 4, 11 and 14 of the DPCO 2013. This makes it abundantly clear that formulations otherwise not forming part of the schedule, upon such orders being issued, became scheduled formulations under paragraph 2(zb) of the DPCO 2013, for which ceiling price as defined in paragraph 2(d) thereof, was fixed.

30. We are of the opinion that the said documents and the manner of exercise of power and interpretation by the parent Ministry itself shows that if a formulation was not specifically included in the first schedule to DPCO 2013, respondent No.3-NPPA could not insist on such a formulation being covered by a ceiling price.

31. The documents on record show a number of illustrations strengthening the said interpretation and implementation of DPCO 2013. For instance, the formulation of medicine Nifedipine was originally included in the first schedule to DPCO 2013, which

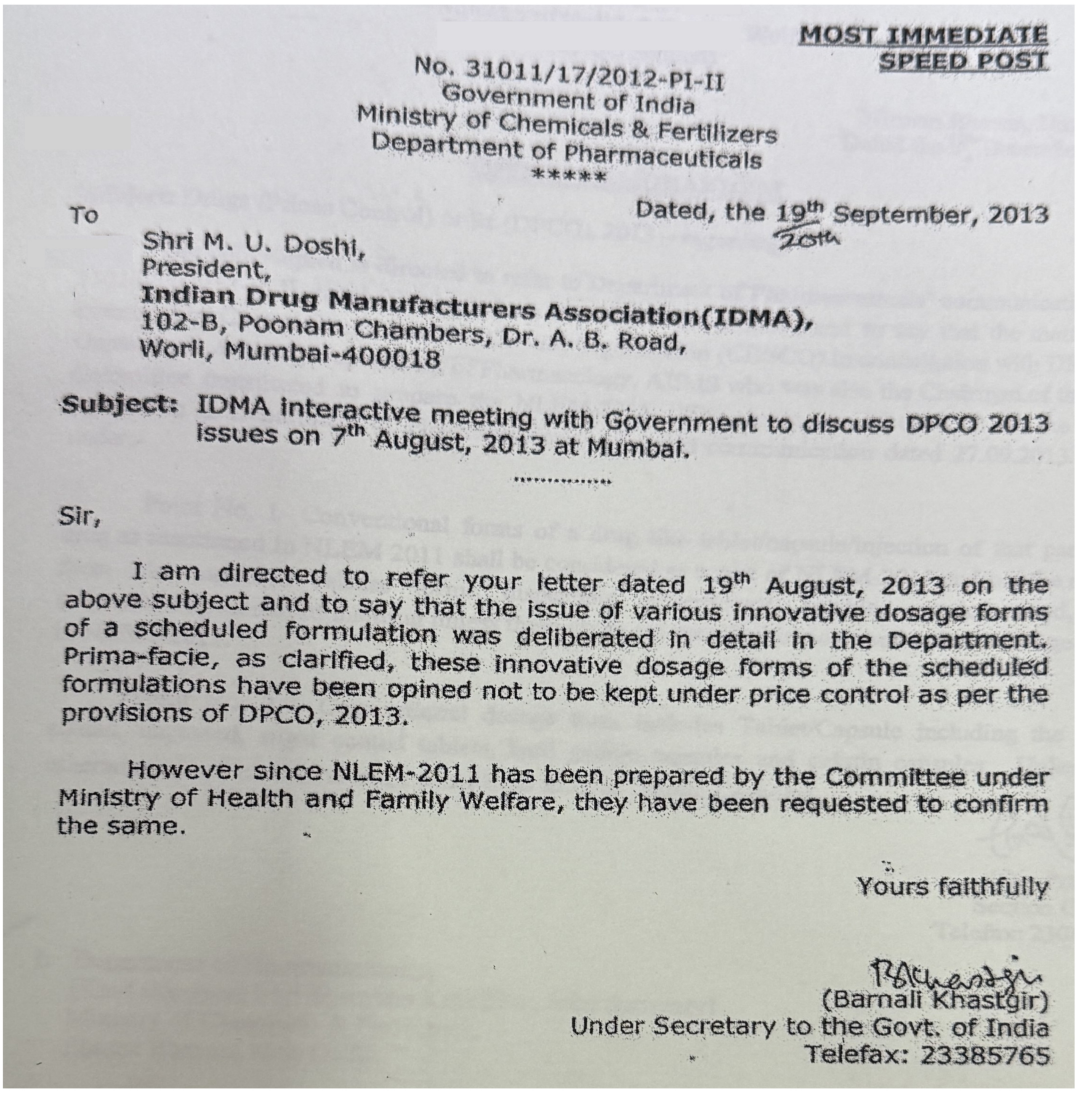
came into force on 15.05.2013. But, thereafter, the respondent-Union of India through the Ministry of Chemicals and Fertilizers (Department of Pharmaceutical) i.e. parent Ministry considered it necessary to invoke powers in paragraphs 4, 11 and 15 of the DPCO 2013 to issue a specific order on 14.06.2013 to include Nifedipine tablets of 10 mg with ceiling price. A few days thereafter, on 28.06.2013, the said respondent again exercised the said power under DPCO 2013 to issue a specific order to include the Nifedipine sustained release tablets 10 mg in the first schedule along with ceiling price. Again a few days thereafter, the said respondent exercised the said power under DPCO 2013 to issue a specific order on 05.07.2013 to include Nifedipine sustained release tablets 20 mg with ceiling price, in the first schedule to DPCO 2013. In the interregnum, on 28.06.2013 also such powers were exercised by issuing order to add Nifedipine capsules 5 mg in the first schedule to DPCO 2013. Thereafter, on 20.09.2013, the said respondent issued separate orders for including Nifedipine sustained release capsules 10mg and 20mg in the said schedule with ceiling price. Similarly, such a specific order was also issued on 28.06.2013 by the said respondent to include Diclofenac 50 mg tablets with ceiling price, in the said schedule. As regards the petitioner in Writ Petition No. 2216 of 2015, it is specifically pointed out that while Metformin 500 mg tablets were specifically included in the schedule by a separate order issued by the said respondent on 21.06.2013, no such order was ever issued for Metformin/Glyciphage SR 500 mg tablet with ceiling price.

32. We find substance in the contention of the petitioners that the said actions of the parent Ministry clearly show as to the manner in which DPCO 2013 is required to be interpreted in the light of the specific policy of 2012. We find that a plain reading of DPCO 2013 and the first schedule appended thereto, as also the subsequent specific orders issued by the parent Ministry i.e. Ministry of Chemicals and Fertilizers (Department of Pharmaceutical) of the respondent-Union of India, show that unless a specific formulation with the drug delivery system was expressly included in the first schedule, the respondent No.3-NPPA could not have insisted on price ceiling. As a matter of fact, the separate ceiling prices for the specific formulations included in the first schedule demonstrate that the methodology and technique used for manufacturing distinct formulations was taken into account, while fixing the ceiling price.

33. This demonstrates the fallacy in the stand taken by the respondents before this Court that where specific drug delivery systems such as Sustained Release (SR) and Controlled Release (CR) were not mentioned in the first schedule of DPCO 2013, then all forms of drug delivery systems of that medicine stood included in the schedule. This is completely unworkable in the light of the separate ceiling prices fixed, while including formulations with different drug delivery systems for the same medicine by issuing specific subsequent orders for including them in the first schedule appended to DPCO 2013. Hence, the said

stand taken on behalf of the respondents is found to be unsustainable.

34. Apart from this, there is substance in the contention raised on behalf of the petitioners that respondent No.3-NPPA cannot defy the clarification and interpretation given by the parent Ministry i.e. the Ministry of Chemicals and Fertilizers (Department of Pharmaceutical) in the communication dated 19/20.09.2013. The same is reproduced as follows :



MOST IMMEDIATE
SPEED POST

No. 31011/17/2012-PI-II
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
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To

Dated, the 19th September, 2013
20th

Shri M. U. Doshi,
President,
Indian Drug Manufacturers Association(IDMA),
102-B, Poonam Chambers, Dr. A. B. Road,
Worli, Mumbai-400018

Subject: IDMA interactive meeting with Government to discuss DPCO 2013 issues on 7th August, 2013 at Mumbai.

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Sir,

I am directed to refer your letter dated 19th August, 2013 on the above subject and to say that the issue of various innovative dosage forms of a scheduled formulation was deliberated in detail in the Department. Prima-facie, as clarified, these innovative dosage forms of the scheduled formulations have been opined not to be kept under price control as per the provisions of DPCO, 2013.

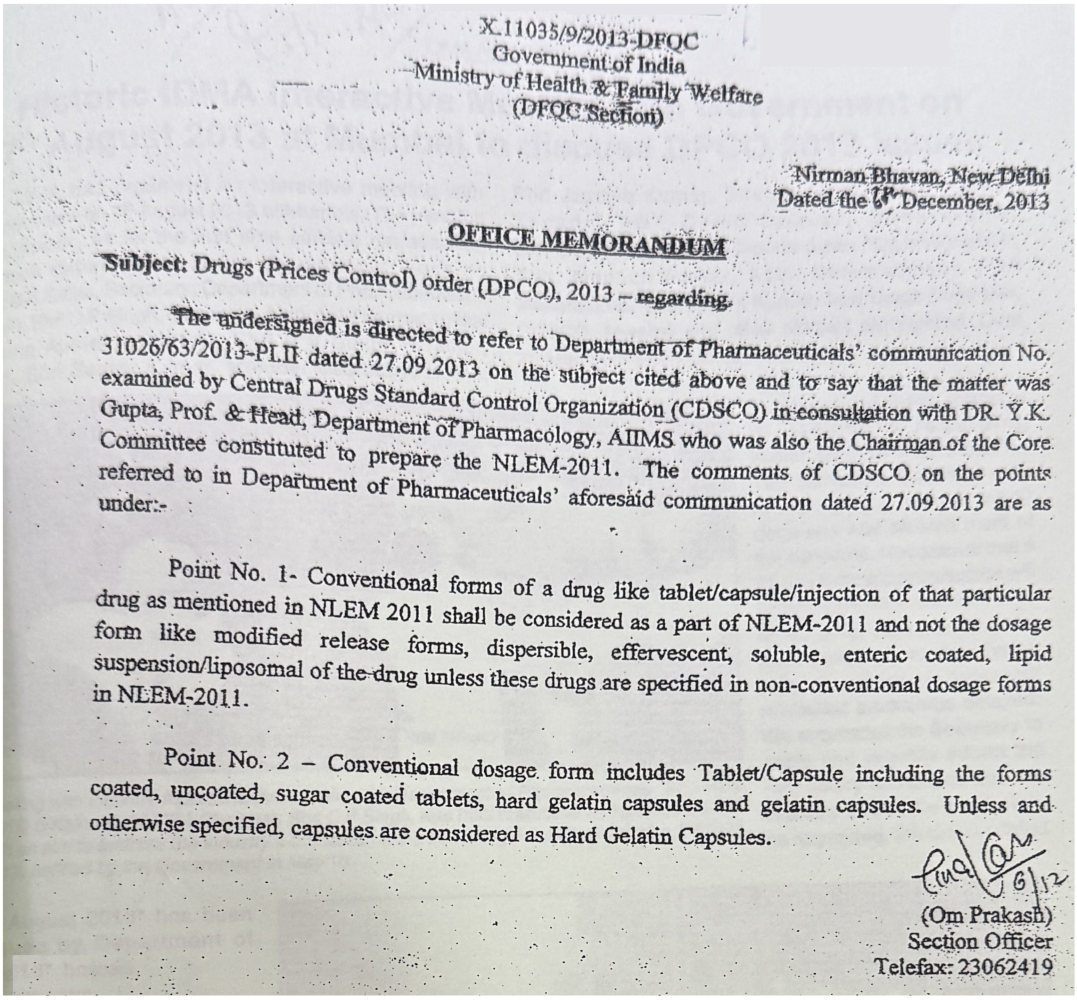
However since NLEM-2011 has been prepared by the Committee under Ministry of Health and Family Welfare, they have been requested to confirm the same.

Yours faithfully

(Barnali Khastgir)
Under Secretary to the Govt. of India
Telefax: 23385765

35. It is significant to note that since a confirmation was

requested from the Ministry of Health and Family Welfare, it was necessary to await the same. Thereafter, on 06.12.2013, the Ministry of Health and Family Welfare issued the following office memorandum :



X.11035/9/2013-DFQC
Government of India
Ministry of Health & Family Welfare
(DFQC Section)

Nirman Bhavan, New Delhi
Dated the 6th December, 2013

OFFICE MEMORANDUM

Subject: Drugs (Prices Control) order (DPCO), 2013 – regarding.

The undersigned is directed to refer to Department of Pharmaceuticals' communication No. 31026/63/2013-PLII dated 27.09.2013 on the subject cited above and to say that the matter was examined by Central Drugs Standard Control Organization (CDSCO) in consultation with DR. Y.K. Gupta, Prof. & Head, Department of Pharmacology, AIIMS who was also the Chairman of the Core Committee constituted to prepare the NLEM-2011. The comments of CDSCO on the points referred to in Department of Pharmaceuticals' aforesaid communication dated 27.09.2013 are as under:-

Point No. 1- Conventional forms of a drug like tablet/capsule/injection of that particular drug as mentioned in NLEM 2011 shall be considered as a part of NLEM-2011 and not the dosage form like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal of the drug unless these drugs are specified in non-conventional dosage forms in NLEM-2011.

Point No. 2 – Conventional dosage form includes Tablet/Capsule including the forms coated, uncoated, sugar coated tablets, hard gelatin capsules and gelatin capsules. Unless and otherwise specified, capsules are considered as Hard Gelatin Capsules.

6/12

(Om Prakash)
Section Officer
Telefax: 23062419

36. It is relevant to note that the said office memorandum was marked to the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and the National Pharmaceutical Pricing Policy of the said department. In the face of such documents, the respondent No.3-NPPA is not justified in taking a completely contrary stand.

37. We also find substance in reliance placed to a limited extent on behalf of the petitioners on the recent judgment of this Court in the case of *Pfizer Ltd. & Anr. vs. Union of India & Ors.* (**supra**). Although, the said case was decided in the context of subsequent notifications and an explanation appended to NLEM 2015, this Court had an occasion to consider a similar argument to the effect that all tablets would cover sustained release or extended release or dispersible tablets and it was found that the same was not in consonance with the specific explanation. In the process, this Court also considered specific drug delivery systems as distinct from an ordinary tablet and in that context, made certain observations. We find that the observations made therein, do support the stand taken on behalf of the petitioners in these writ petitions. Although, according to us, even a plain reading of DPCO 2013 along with specific subsequent orders issued for adding formulations with different drug delivery systems to the first schedule, demonstrates that unless a formulation with a specific drug delivery system stood included in the first schedule with price ceiling, the respondent No.3-NPPA could not insist upon ceiling price and that the allegation of overcharging was rendered unsustainable.

38. As regards the judgments relied upon by the respondents in the cases of *Union of India & Anr. vs. Cynamide India Ltd. & Anr.* (**supra**), *Glaxosmithkline Pharmaceuticals Limited vs. Union of India & Ors.* (**supra**) and judgment of this Court in the case of

Indian Pharmaceutical Alliance & Anr. vs. Union of India & Ors. (**supra**), there can be no quarrel with the general proposition that the Court should not interfere when prices or ceiling prices are fixed by the Government under such drug price control orders issued under the provisions of the Essential Commodities Act, 1955. But, the fixing of such ceiling prices obviously has to be in accordance with the policy and the drug price control orders issued by the respondent-Union of India. It cannot be that when the policy and the drug price control order specifies a particular manner of identifying medicines for fixing ceiling prices, the NPPA can insist on price ceiling in the teeth of the same. Hence, where it is found that such policy is being arbitarily implemented, the writ Court can certainly interfere.

39. We find that in the present case, the stand taken by the respondent No.3-NPPA is against the interpretation of the DPCO 2013 issued by the parent Ministry i.e. respondent-Union of India through the Ministry of Chemicals and Fertilizers (Department of Pharmaceutical) and hence, the impugned notices and demands are rendered unsustainable.

40. Reliance placed on judgments of the Supreme Court in the case of *T.C. Healthcare Private Limited & Anr. vs. Union of India & Anr.* (**supra**) is also misplaced because in the said case, the Supreme Court was considering the contentions of the rival parties in the context of DPCO 1995. As noted hereinabove, in DPCO 2013, a clear departure was made from DPCO 1995, in the light

of the National Pharmaceutical Pricing Policy 2012 issued by the respondent-Union of India, as per notification dated 07.12.2012. The contentions of the rival parties in these writ petitions have to be considered on the basis of such changed policy and the specific contents of DPCO 2013, read with the first schedule.

41. In view of the above, the writ petitions deserve to be allowed.

42. Accordingly, Writ Petition No. 885 of 2015 is allowed in terms of prayer clauses (a), (b) and (c). Writ Petition No.2216 of 2015 is allowed in terms of prayer clause (a). As regards prayer clause (b), it is held that the notification dated 21.06.2013 at Exhibit 'B' to the said petition cannot be the basis for issuing the impugned demand notice dated 16.01.2015.

43. Pending applications and notices of motion, if any, also stand disposed of.

(SHREERAM V. SHIRSAT, J.) **(MANISH PITALE, J.)**