Kee Pharma Limited vs National Pharmaceutical Pricing ... on 23 September, 2025

Author: Sachin Datta

Bench: Sachin Datta

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*     IN THE HIGH COURT OF DELHI AT NEW DELHI
+         W.P.(C) 14728/2025 and CM APPL.60459/2025
          KEE PHARMA LIMITED
                       Through:                       Ms
                       versus

          NATIONAL PHARMACEUTICAL
          PRICING AUTHORITY & ANR.                 .....Re
                       Through: Ms. Saumya Tandan (CGSC) along
                                with Mr. Rudra Paliwal (GP)
                                R1 & R2
                                Mr. Sushil Tekriwal, Dr. Mam
                                Tekriwal, Advs. for R4.
          CORAM:
          HON'BLE MR. JUSTICE SACHIN DATTA
                       ORDER
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% 23.09.2025 CM APPL.60460/2025 (seeking leave to file lengthy synopsis and list of dates and events)

1. Allowed, subject to all just exceptions.

2. Application stands disposed of.

W.P.(C) 14728/2025 & CM APPL. 60459/2025 (Interim Relief)

3. The present petition has been filed by the petitioner, a pharmaceutical company seeking the following prayers:

> "a) Issue a writ of certiorari or any other appropriate writ, order or direction setting aside and quashing the Impugned Office Memorandum dated June 09, 2017, issued under Ref. No. F. 19(1064)/2016/DP/Div.II/NPPA, by the NPPA - Respondent No.1 herein, to the limited extent the same pertains to non-scheduled formulations, and restrain the Respondents, its servants and agents from enforcing the said notice or acting thereupon in any manner;
>
> b) Issue a writ of certiorari or any other appropriate writ, order or direction setting aside/ quashing the Impugned Demand Notice dated This is a digitally signed order.

July 11, 2025, issued by Respondent no. 1 - National Pharmaceutical Pricing Authority, as being arbitrary, illegal and having been issued without application of mind

c) Pending hearing and final disposal of this petition, the Hon'ble Court be pleased to restrain the Respondents by themselves or through their officers, servants or agents from interfering with the business of the Petitioners or from initiating / taking any coercive steps against the Petitioners for enforcing the demands raised pursuant to the Impugned Demand Notice"

4. The factual matrix as set forth by the petitioner is that the petitioner is engaged in the manufacturing and marketing the pharmaceutical formulation "Diclofenac 50mg + Paracetamol 325mg + Chlorzoxazone 250mg", under the brand name "DOLOCIDE-MR tablets" which is a 'non-scheduled formulation' under the provisions of the Drugs (Prices Control) Order, 2013 (hereinafter referred to as "DPCO 2013").

5. It is the petitioner's case that following the implementation of the Goods and Service Tax (GST), whereby, tax rate applicable on medicines was increased from 6% to 12%,the respondent no.1/ National Pharmaceutical Pricing Authority (NPPA) issued the impugned Office Memorandum (OM) dated 09.06.2017. The said memorandum permitted manufacturers of scheduled formulations to revise ceiling prices by applying a factor of 0.95905, whereas manufacturers of non-scheduled formulations were directed to strictly comply with the provisions of DPCO 2013, irrespective of changes in tax structure. The memorandum further stated that manufacturers of non-scheduled formulations would be required to absorb any net increase in tax incidence.

6. Learned counsel for the petitioner submits that the impugned office memorandum is beyond the jurisdiction of NPPA inasmuch as the NPPA does not have the authority to fix or regulate such prices, except in

accordance with the provisions of the DPCO 2013.

7. It is further submitted that the impugned office memorandum discriminates between scheduled and non-scheduled formulations by permitting the former to pass on the increased tax burden to consumers, while compelling the latter to absorb the same.

8. On 22.09.2020, the NPPA issued a notice to the petitioner alleging non-compliance with Paragraph 20 1 of the DPCO 2013, citing a price increase of 14.12% between April 2017 to April 2018, which allegedly exceeded the permissible limit of 10%. The petitioner responded vide letter dated 09.10.2020, enclosing batch-wise production and sales data from May 2013 to 2020.

9. Thereafter, on 01.12.2020, despite the petitioner's reply dated 09.10.2020, the NPPA issued a 'reminder letter' which was duly replied to on 12.12.2020. Subsequently, on 06.03.2025, the NPPA

issued a show cause notice alleging overcharging in respect of batches manufactured between September 2017 to February 2024, and called upon the petitioner to show cause as to why the overcharged amount of Rs. 22,21,771/-, along with interest, be not recovered from the petitioner.

10. The petitioner contends that the relevant data had already been submitted in its earlier reply dated 09.10.2020, and that the NPPA's refusal to consider the same on the ground of lack of CA certification is unjustified.

20. Monitoring the prices of non-scheduled formulations.- (1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the nonscheduled 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.

 It is further submitted that the NPPA proceeded to calculate the alleged overcharged amount based on undisclosed information.

11. On 31.03.2025, the petitioner submitted an interim response seeking four weeks' time to furnish a detailed reply, which was subsequently submitted on 15.05.2025. However, the NPPA issued a 'demand notice' dated 11.07.2025, directing the petitioner to deposit Rs.32,59,526/- towards the alleged overcharged amount and Rs. 31,41,463/- towards interest calculated thereon.

12. It is submitted that the calculation sheet appended to the impugned demand notice does not correspond with the production details furnished by the petitioner, and the basis of computation adopted by the NPPA remains undisclosed. The petitioner further contends that the NPPA has disregarded the CA-certified data without providing any rationale.

13. It is further submitted that "while a number of formulations have not been included in the First Schedule of the DPCO 2013, fixation of MRP in relation to such non-scheduled formulations is left to market forces and, in fact, governed by the principle of "Forbearance", viz. not requiring any intervention by the NPPA for fixing the ceiling price."

14. Learned counsel for the petitioner has also made reference to the National Pharmaceutical Pricing Policy (NPPP), 2012, which forms the basis of DPCO 2013. The relevant extract of the NPPP, 2012 is reproduced as under:

> "(xii) Non-price Control Drug: 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 fixes the price 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 This is a digitally signed order.

The authenticity of the order can be re-verified from Delhi High Court Order Portal by scanning the QR code shown above. The Order is downloaded from the DHC Server on 03/10/2025 at 22:18:47 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 above10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for the next 12 months."

15. By way of the C.M. Application No. 60459 of 2025, the petitioner has prayed for interim relief in the present petition. In this regard, attention is drawn to the order dated 03.09.2025, passed by this Court in W.P(C).11459/2025, titled 'Kee Pharma Limited v. National Pharmaceutical Pricing Authority & Anr', which pertains to a similarly placed matter involving the same parties as in the present petition.

16. Considering the averments and in view of the order dated 03.09.2025, the application is allowed.

17. Issue notice.

18. Learned counsel, as aforesaid, accepts notice on behalf of the respondent.

19. Let reply be filed within a period of four weeks from today. Rejoinder thereto, if any, be filed within a period of three weeks thereafter.

20. In the meantime, considering the aforesaid circumstances highlighted by the learned counsel for the petitioner, it is directed that till the next date of hearing, no coercive steps shall be taken against the petitioner pursuant to the impugned demand notice dated 11.07.2025.

21. List on 22.12.2025.

SACHIN DATTA, J SEPTEMBER 23, 2025/ss This is a digitally signed order.

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