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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **W.P.(C) 5078/2018 & CM No. 19639/2018**

LIFECARE INNOVATIONS PVT. LTD. Petitioner

Through: Mr Anil Kaushik, Mr Abhishek
Misrha and Mr Akash Bhardwaj,
Advocates.

versus

UNION OF INDIA AND ORS. Respondents

Through: Mr Ravi Prakash, CGSC, Mr Varun
Pathak and Mr Farman Ali,
Advocates.

CORAM:

HON'BLE MR. JUSTICE VIBHU BAKHRU

ORDER

% 05.02.2019

1. The petitioner has filed the present petition being aggrieved by the non-implementation of the recommendations of the Core Committee constituted by the Ministry of Health and Family Welfare (hereafter 'the Core Committee'). The controversy in the present case relates to the action of respondent no.2 (National Pharmaceutical Pricing Authority – NPPA) in clubbing the Liposomal and Lipid formulations of Amphotericin B and Conventional Amphotericin B as one category in Schedule I of the Drug (Prices Control) Order, 2013 (DPCO – 2013). It is the petitioner's case that the three drugs – Lipid Amphotericin B (hereafter 'Lipid AmB'), Liposomal Amphotericin B (LAmB) and Conventional Amphotericin B (CAmB) are three separate and distinct drugs. It is claimed that the manufacturing process, usage, form, clinical efficacy and toxicity are also different. Admittedly, the prices of the said formulations also vary significantly.

2. DPCO-2013 was notified on 15.01.2013 and Clause 6.3 of Schedule I to DPCO-2013 listed Amphotericin B as a single category, without making any distinction between the 'LAmB', 'Lipid AmB' and 'CAmB'.
3. Subsequently, NPPA also issued a price notification order dated 28.06.2013, fixing the same ceiling price for 'LAmB', 'Lipid AmB' and 'CAmB'.
4. The price was revised by the subsequent price notification order dated 28.04.2014. The petitioner filed a petition seeking review of the same which was rejected by an order dated 18.06.2015.
5. Aggrieved by the price notification orders and the order dated 28.04.2014, the petitioner filed a writ petition – ***W.P.(C) 8053 of 2015*** captioned "***Lifecare Innovations Pvt. Ltd. v. Union of India and Anr.***". The said writ petition was withdrawn by the petitioner on 11.07.2017 in view of subsequent developments. However, the petitioner reserved its right to continue to agitate the contentions advanced in the aforesaid petition.
6. In the meanwhile, the Core Committee published the National List of Essential Medicines, 2015 (NLEM-2015), wherein CAmB was classified separately but Lipid AmB, LAmB continued to be clubbed under the same category.
7. By a notification dated 10.03.2016, NLEM-2015 was substituted in place of NLEM-2011 as Schedule I to DPCO-2013.
8. Aggrieved by the same, the petitioner filed a writ petition (being W.P.(C) 6131/2013) impugning the action of NPPA of clubbing Lipid AmB

and LAmB in one category. On 10.03.2017, NPPA issued another price fixing order, fixing the ceiling price of CAmB as a separate category and a ceiling price for LAmB and Lipid AmB.

9. The petitioner impugned the same by filing another writ petition – W.P.(C) 2923/2017. The aforementioned writ petition was disposed of by this Court by a common order dated 17.07.2017, permitting the petitioners to file a detailed representation with all necessary documents and further directing that the Core Committee to consider the same within a period of six weeks thereafter.

10. The respondents have filed an affidavit which indicates that NPPA has accepted the recommendations of Core Committee dated 02.04.2018 and is accordingly, willing to categorise the subject drugs for pricing purposes. It is also stated that the petitioner company had not provided the requisite data and in absence of copies of invoices in support of the PTR (Price to Retailer) and MAT (Moving Annual Turnover) data for the month of August, 2015, the respondents are not in a position to fix the separate ceiling price for LAmB as recommended by the Core Committee.

11. Mr Kaushik, the learned counsel appearing for the petitioner submits that price fixation has to be done, by keeping in view the prices as prevailing on 15.05.2013 (the date on which the DPCO, 2013 had come into force) or the pricing data immediately prior to that and not the prices as on August 2015. This is so as during the said period, the petitioner was compelled to sell below the ceiling price, which was impugned by the petitioner. The learned counsel appearing for the respondents disputes the same. He

submits that the price fixation has to be prospective and not retrospective.

12. As noticed above, the principal grievance of the petitioner stems from the action of the respondents in clubbing LAmB, Lipid AmB and CAmB in the same category for fixing the ceiling price. As noticed above, the said challenge was considered by this Court in the Writ Petitions (W.P.(C) Nos.6131/2016 and 2923/2017). The said petitions were disposed of by an order dated 17.07.2017, as the learned counsel appearing for the respondents has produced a note which indicated that the Ministry of Health and Family Welfare has examined the contentions and accepted that the formulation LAmB was not the same as CAmB or Lipid AmB and, therefore, the same could not be considered in a single category. It is material to note that this Court had also observed in its order that the pleadings in the writ petition to the effect that LAmB, Lipid AmB were materially different, had remained uncontroverted

13. In view of the aforesaid, this Court had disposed of the writ petition by permitting the petitioner to make a detailed representation alongwith the necessary documents and further directing the Core Committee to examine the same within a period of six weeks, thereafter.

14. This Court had also directed that if the petitioner's grievance with regard to the categorization is addressed, the respondent would also examine the issue of price fixation after affording the petitioner an opportunity to be heard.

15. It is clear from the affidavit filed by the respondent that the petitioner's grievance regarding being categorized in a single category

alongwith CAmB (Conventional Amphotericin B) and Lipid AmB (Lipid Amphotericin B) has been addressed, as it is accepted that the formulations cannot be placed in a single category.

16. In view of the above, the only question that remains to be considered is with regard to the price fixation of LAmB. If LAmB is to be separately classified – as is now accepted by NPPA – its ceiling price would also have to be determined in accordance with the provisions of the DPCO, 2013, without reference to the prices of Lipid AmB and CAmB. As on date, NPPA has not fixed any specific price for LAmB as it had not accepted that the said drug was required to be classified separately. Now that the petitioner's claim that LAmB is a separate drug and requires to be classified separately from CAmB and Lipid AmB has been accepted, it stands to reason that the price fixed earlier cannot be applied. In the event the respondents desire to fix the ceiling price for LAmB, it would be necessary for the respondents to examine the relevant data and fix the same.

17. The learned counsel appearing for the respondents contends that the said price can only be fixed prospectively. This contention is unpersuasive. The petitioner's challenge in the writ petitions filed earlier was, *inter alia*, with regard to clubbing of LAmB with other formulations (CAmB and Lipid AmB) for fixation of a common ceiling price. Its contention has been accepted. Thus, the ceiling price so fixed earlier cannot be accepted to be applicable. It is also relevant to note that the methodology of price fixation followed in DPCO, 2013, is to take the mathematical average of the price based on market data. Once it is accepted that the two formulations cannot be categorized as one, the question of clubbing the respective data of the

formulations for fixing the ceiling price also does not arise.

18. This Court has not interfered with the petitioner's challenge to price fixation in W.P.(C) 6131/2016 and W.P.(C)2923/2017, since the petitioner's contention that LAmB ought to be categorized separately had not been finally accepted. That issue having now been resolved with NPPA accepting the recommendations of the Core Committee, the consequential relief relating to price ought to necessarily follow. Plainly, if the petitioner is correct that LAmB cannot be clubbed with other medicines, the price fixed for LAmB, which is based on the price of other formulations also cannot be sustained.

19. In view of the above, this Court considers it apposite to direct NPPA to re-compute the ceiling price as applicable to the LAmB as per the procedure as provided under DPCO, 2013. The petitioner is directed to provide all data as required by NPPA for the said purpose. NPPA is also not precluded from obtaining the relevant data from other sources, as it may consider necessary. It is clarified that the ceiling prices shall be fixed keeping the data as available at the material time in 2013. Let the same be done within a period of six weeks from today.

20. The petition is disposed of with the aforesaid observations. The pending application is also disposed of.

21. Order *dasti* under signatures of the Court Master.

VIBHU BAKHRU, J

FEBRUARY 05, 2019/MK