No.31015/44/2023-Pricing (E-23444)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
.....

Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Pfizer Limited (hereinafter called the "Applicant") filed a Review Application dated 02.03.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 484(E) dated 02.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Prednisolone tablets.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 06.11.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the Applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The company is engaged in the manufacture and marketing of various pharmaceutical products, including Wysolone DT tablets (in SKU's of 5mg 10mg & 20mg) containing "Prednisolone" which are all dispersible tablets. Wysolone DT was included under the NLEM 2011 and in Schedule-I of DPCO, 2013 and as such at the relevant time, the same was a scheduled formulation under DPCO, 2013. Schedule-I of DPCO, 2013 was amended by Notification S.O. 701(E) dated 10th March, 2016 which essentially substituted NLEM 2011 with NLEM 2015 with effect from 10th March 2016. In view of such amendment and more particularly Explanation (1) and (2) thereto, the Applicant's Wysolone DT (being a dispersible tablet) was excluded from NLEM, 2015 and became a non-scheduled formulation under DPCO, 2013. NPPA, however, was of the view that 'Wysolone DT' was covered under the NLEM, 2015 and was subject to the rigours of DPCO 2013, being a scheduled formulation. Despite various communications and clarifications provided by the Applicant, NPPA continued to persist with this view. NPPA further proceeded to issue show cause notice dated 8 March 2018 followed by demand notice dated 20 June 2018 against the Company. The Company has inter alia challenged the said show cause notice and demand notice before the Hon'ble Bombay High Court by filing Writ Petition No. 2519 of 2018 titled Pfizer Limited & Anr vs. Union of India, Ministry of Health &

Family Welfare & Ors. The Hon'ble Bombay High Court by a reasoned order dated 4 September 2018 granted ad-interim reliefs and inter alia held:

> *"12. ..... However, we have ourselves independently, by applying the first principle of interpretation, come to the prima facie conclusion that insofar as innovative formulation are concerned, unless they are specifically mentioned in the Schedule against the name of the medicine, the same will not be covered by the said Order. It is not necessary to mention that the Order issued by exercising powers under Section 3 of the Essential Commodities Act is quasi legislative piece of legislation. The administrative instructions which conflict with quasi legislative piece of legislation, cannot be permitted to supersede the same. 13. We are therefore of the considered view, that the impugned coercive action which is sought to be taken against the Petitioners is not permissible in view of the Interpretation as placed by us hereinabove on Clause (2) of the Explanation to the Schedule of the said order"*

The above order has been continued from time to time and is in force. Thereafter, by order dated 28 March 2022, the Hon'ble Bombay High Court clarified that all subsequent notices/demand issued by NPPA in relation to 'Wysolone DT' are subject to orders of the Court and cannot be acted upon nor can any coercive action be taken against the Company. This writ petition is pending hearing and final disposal.

3.2 Recently, vide Notification S.O. 5249 (E) dated 11 November 2022, the DPCO, 2013 has been amended. Vide this amendment Schedule-I to the DPCO, 2013 (i.e., NLEM, 2015), has been substituted with the new amended NLEM, 2022. Under the NLEM, 2022 Prednisolone formulations are listed under Sections 3.6, 7.2.4, 18.1.5 and 21.2.1. Under the amended NLEM, 2022 it is stated that *"All modified release formulations of same strength such as sustained release, controlled release, extended release, prolonged release etc. are included."*

3.3 Whilst the Applicant was examining the applicability of the above amendment and seeking advice thereon, the Company learnt of the NPPA Office Memorandum No. 12/ (90)/2022/DP/NPPA/Div.-II dated November 25, 2022, inviting comments on the draft working sheets of calculation of ceiling process which would be uploaded by NPPA (on its website) for formulations under the revised NLEM, 2022. NPPA thereafter on December 1 and 2, 2022, uploaded on its website, draft working sheets of calculations. One such formulation which is reflected in one of the working sheets of calculations for Prednisolone 5mg Tablets is 'Wysolone 5mg DT', Prednisolone 10mg Tablets is 'Wysolone 10mg DT' and Prednisolone 20mg Tablets is 'Wysolone 20mg DT'.

3.4 In view of the abovementioned Office Memorandum, the Applicant, without prejudice to its rights and contentions, was constrained to make representations against inclusion of formulation "Wysolone DT Tablets (5mg, 10mg & 20mg)", vide its letters of December 14, 2022 (forwarded via email of the same date) on the following grounds:

(a) The Company's formulation 'Wysolone DT' has been incorrectly shown in the calculation for the formulation 'Prednisolone 5mg, 10mg & 20mg' for plain tablets; and

(b) Without prejudice to the above submission, the Applicant's formulation's Price to Retailer (PTR) of INR 0.71 per unit, INR 1.29 per unit & INR 2.31 per unit have not been reflected in the draft working calculation of ceiling prices for Prednisolone 5mg plain tablets, Prednisolone 10mg plain tablets and Prednisolone 20mg plain tablets respectively to its actual rate without any limitation or reduction and as such the draft calculations are erroneous and cannot be acted upon.

3.5 However, in complete disregard to the representations made by the Company, NPPA issued price Notification on February 2, 2023, fixing the ceiling price of Prednisolone 5mg plain tablets – 1 tablet at Rs. 0.61, Prednisolone 10mg plain tablets – 1 tablet at Rs. 1.07 and Prednisolone 20mg plain tablets – 1 tablet at Rs. 2.14. This is the same ceiling price as contained in the draft working calculation.

3.6 The Applicant stated that whilst, the NLEM, 2022 now seeks to cover as 'scheduled formulations' even modified release formulations of the formulations in the same strength, though dosage is not specified, there can be no dispute that 'plain tablets' and 'dispersible tablets' are different dosage forms. This was clearly understood as such under the DPCO, 1987 and DPCO 1995. This position continued in the DPCO, 2013 as well. In fact, Schedule-I to the DPCO, 2013, which was amended by Notification S.O. 701 (E), dated 10 March 2016, (which essentially substituted NLEM 2011, with NLEM, 2015), inter alia, at Explanation (2), specifically excluded sustained release/controlled release formulations, etc; this was because it was clearly understood that such dosage forms apart from being incremental innovations were clearly different dosage forms.

3.7 Para 11 of the DPCO, 2013 also requires ceiling price or retail price of a pack to be calculated on dosage basis (i.e., tablet, capsule, etc.). Therefore, a dispersible tablet being a different basis of dosage than a plain tablet, the ceiling price would be required to be calculated separately. Furthermore, the Explanation to NLEM, 2022 also makes it abundantly plain and clear, that different dosage forms are to be treated differently for the purpose of pricing, etc.

3.8 In view of the aforesaid, the Applicant's formulation 'Wysolone DT Tablets (5mg, 10mg & 20mg)' which contains 'Prednisolone', being a dispersible tablet, a different dosage form, could not and cannot be equated with a plain tablet. Accordingly, their prices should not have been included in the NPPA calculation of the ceiling price under para 4 of DPCO, 2013 of the plain tablets. The calculation is therefore contrary to DPCO, 2013. Therefore, the ceiling price as fixed vide the Notification is erroneous and cannot be relied upon for either 'Prednisolone' plain tablet or 'Prednisolone' dispersible tablet.

3.9 The Applicant's formulations PTR of INR 0.71 per unit, 1.29 per unit and 2.31 per unit Prednisolone 5mg plain tablets, Prednisolone 10mg plain tablets and Prednisolone 20mg plain tablets respectively, have not been reflected in the draft

working calculation of ceiling prices to its actual rate without any limitation or reduction as such the draft calculations are erroneous and cannot be acted upon. In view thereof, the fixation of ceiling price as fixed vide the Notification (based on the NPPA working) is in turn erroneous and cannot be relied upon for either 'Prednisolone' plain tablet or 'Prednisolone' dispersible tablet. The Applicant maintained that the price to retailer as mentioned herein is admitted by NPPA.

3.10 The Applicant submitted that the ceiling price notified vide the Notification under review is erroneous and cannot be applied to the them. NPPA, despite the Company's earlier representations, proceeded to fix the ceiling price.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 The methodology approved and followed for the pricing of MR Variant/Conventional Variant by the Authority is as below:

> *"Wherever, MR variant is specifically mentioned in any formulation the data of only MR variants (CR, SR, XL, ER delayed release etc.) may be considered for fixation of ceiling price. However, where MR variant is not specifically mentioned, data of conventional as well as MR variants may be considered for ceiling price fixation. This is in line with methodology of NLEM 2015 also. Similarly, where DT/effervescent/soluble/MD, etc. is specifically mentioned in any formulation the data of only such variants may be considered. However, in absence of any variant being specifically mentioned, the DT/effervescent /soluble/MD may be considered along with conventional form"*

Further, the above methodology is same as was followed for fixation of ceiling prices under NLEM 2015. (Reference 105th Authority meeting).

4.2 The MR variants form an integral part of essential and lifesaving drugs and taking them out of price control is not the objective of SNCM. NLEM as well as Revised Schedule-I of DPCO, specifically mentions as below:

"All modified release formulations of same strength such as sustained release, controlled release, extended release, prolonged release etc. are included."

4.3 Further, this methodology followed in relation to conventional / modified releases is same as followed for fixation of ceiling prices under NLEM 2015. Examples are:

Case 1: Formulation appearing in Schedule-I: Metformin 500mg

Since, the variant i.e. conventional / modified is not stated in Schedule-I, all variants were considered included in Schedule-I and the ceiling price was fixed considering all the variants. Further, the ceiling price was applicable to all variants.

Case 2: Formulation appearing in Schedule-I: Metformin 1000mg and Metformin 1000mg MR

Since, both variants i.e. conventional and MR are specifically stated in the schedule, separate prices were fixed for both i.e. conventional and non-conventional variant. If the petitioner's suggestion is considered, the prices of Modified releases will not be covered under Schedule-I in case where only conventional variants are mentioned and will make the MR variants of the formulation de-regulated.

4.4 Further, with respect to writ petition pending in Hon'ble High Court of Bombay, it is stated that the petitioner company have been granted stay on the Show Cause Notice/Demand notice dated 8.3.2018,15.3.2018 and 20.6.2018. However, the issue of Wysolone DT is still to be decided/sub-judice before the Hon'ble Court. Further as per Counter Affidavit and Sur rejoinder, NPPA's stand has always been that Wysolone DT is included in NLEM and is within the ambit of price control.

5. Examination:

5.1 The National List of Essential Medicines (NLEM) prepared by Standing National Committee on Medicines (SNCM) under Ministry of Health and Family Welfare (MoH&FW) forms the very basis of Schedule-I of the DPCO 2013, which is amended, whenever the NLEM is revised. The latest NLEM (2022) was notified on 13.09.2022 and accordingly, Schedule-I to DPCO 2013 was revised on 11.11.2022 vide Gazette Notification SO No. 5249 (E).

5.2 The NLEM is prepared with the objective of satisfying the priority health care needs of the population. The list is made based on disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. The aim behind formulating NLEM is to ensure that these medicines are available in adequate quantity, in appropriate dosage forms and strengths with assured quality. NLEM does recognize such innovations in drugs where substantial improvements, effectiveness and efficacy have been introduced either in terms of quality or in the delivery system or both. Accordingly, NLEM mentions such innovative drugs separately under different categories commonly named as Modified Release (MR) versions in the same list where such criteria are fulfilled. When the same is not mentioned separately, then all such varieties of such drugs for the specified dosages are considered to be part of variants appearing in the list. The objective of NLEM, inter alia, is to ensure availability of the essential drugs as well. This objective may be adversely affected by the exclusion of different variants from the NLEM based on criteria such as MR etc., as such exclusion may encourage essential drugs simply moving out of NLEM. This may not be in line with the spirit and purpose of including these drugs in the list of essential medicines in the first instance.

5.3 Further, with respect to writ petition pending in Hon'ble High Court of Bombay, though stay has been granted on the Show Cause Notice / Demand notice dated 8.3.2018,15.3.2018 and 20.6.2018 to the company, the issue of Wysolone DT is yet to

be decided/sub-judice before the Hon'ble Court. Further as per Counter Affidavit and Sur rejoinder, NPPA has reiterated its stand that Wysolone DT is included in NLEM and is within the ambit of price control.

5.4 Therefore, in view of the facts as at paras 5.1 and 5.2 above, arguments and logics given by NPPA are accepted.

6. Decision:

The action of NPPA fixing the ceiling price of subject formulation vide S.O. No. 484(E) dated 02.02.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 10th day of October, 2024.

10/10/2024

(Awadhesh Kumar Choudhary)
Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To

M/s Pfizer Limted
The Capital, 1802 / 1901, Plot No. C-70,
G Block, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051.

Copy to:

1. Chairperson, NPPA, New Delhi
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File