

No. 31015/41/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Alkem Laboratories Ltd. against price fixation of “Uprise 60K IU Soft Gelatin Capsule (Cholicalciferol 60K IU), Cholicalciferol 1000 IU, Taxim O Forte Dry Syrup (Cefixime Oral Liquid 100 mg./5 ml and Cefixime Oral Liquid 50mg/5 ml” vide NPPA order No. S.O. 1687(E) dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 07.06.2016
2) NPPA notification under review S.O. No.1687(E) dated 09.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 25.07.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Alkem Laboratories Ltd. (hereinafter called the petitioner) against notification S.O. No.1687(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Uprise 60K IU Soft Gelatin Capsule (Cholicalciferol 60K IU), Cholicalciferol 1000 IU, Taxim O Forte Dry Syrup (Cefixime Oral Liquid 100 mg./5 ml and Cefixime Oral Liquid 50mg/5 ml.

2. The petitioner has contended as under:

- I. NPPA is yet to act on the rectification of the errors that have crept in while fixing the ceiling prices of the above formulations. **It is pertinent to note that they have implemented the revised ceiling prices as notified by the aforesaid price fixation Notifications dated 9th May and intimated NPPA and the State FDAs accordingly.**
- II. Company is manufacturing and marketing the above said formulations not as a conventional powder filled hard gelatin capsule but as a soft gelatin capsule, which is very much different from conventional capsules in terms of manufacturing process. Hence, company needs a clarification with the effect that whether the above aforesaid notification issued for capsules will apply to their product which is a soft gelatin capsule form.
- III. The above said formulations were introduced for the first time in the revised NLEM 2015. In case the aforesaid Notification dated 9th May 2016 also applies to soft gelatin capsules. They submitted that the fixation of the ceiling price of **Cholicalciferol 60 K IU, Cholicalciferol 1000 IU, Cefixime Oral Liquid 100 mg/5ml and Cefixime Oral Liquid 50 mg/5ml** have not been exercised in accordance with the letter and spirit of the DPCO particularly terms of the provisions of paragraphs 4 and 18 of the DPCO read with the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) issued on 07.12.2012.
- IV. SO 1687 (E) has been issued for ‘fixing’ for the first time the Ceiling Prices in respect of the formulations mentioned therein, which includes their subject

formulation, in view of their inclusion in the revised NLEM 2015. Since the **Ceiling price** is fixed in respect of the subject formulation for the first time, the concept of 'revision' cannot apply and consequently the provisions of paragraphs 16 or 18 – both of which deal with 'revision' cannot be attracted.

- V. **The ceiling price of the subject formulations must be fixed only in accordance with paragraph 4 of DPCO. Once an exercise is conducted under paragraph 4, the question of applying any effect of the WPI change cannot arise. In fixing the ceiling price of the subject formulation, however, the Government has applied a WPI reduction, which they submitted is unfair, unjustified and contrary to the scheme of the DPCO. They submitted that such reduction must not be applied.**
- VI. Without prejudice to the aforesaid, they further submitted that even the ceiling price that has been re-fixed is totally unrealistic and arrived at without taking into account the widely available information in the public domain. The Government is well aware that in the pharmaceutical Industry the actual Retailers' Margin gets fixed based on the relative negotiating capacities of the manufacturers and the trade associations of which such retailers are members. At present, in most cases this Retailers margin has been fixed at 20% of the Maximum Retail Price (MRP), which works out to 25% of the PTR, as opposed to the Retailers' Margin of 16% of the PTR which is used for calculating the ceiling price.
- VII. Without prejudice to what is stated above, while going through the working sheet uploaded by the NPPA, they identify that their products are not appearing in the working of ceiling price. They also provide the PTR and MAT of Uprise D3 soft gelatin capsules as appearing in AWAC Aug 2015.

Product	Pack Size	Strength	MRP	PTR	MAT August 2015
Uprise D3 60K SG Capsules	4 Cap	60000 IU	157.00	120.84	36,86,40,471

- VIII. Also the working sheet is not based on company level MAT %, due to which some products' PTR is not considered in ceiling price calculation. Like Sr. Nos. 9 & 11 both pertain to company Indchemie which are not considered, sr no 13 D3 extra of Macleods is also not considered, and Sr No 26 D All of Torrent is also not considered.
- IX. In the working sheet, it is observed that there are 2 brands of Unichem viz High D3 & Power D3. There appears to be certain anomaly in the PTR of both the brands. In the working sheet of Cholicalciferol 60 KIU the PTR are similar but in the working sheet of Cholicalciferol 1K IU the PTR are different. They hereby presented a tabular view of the same.

Sr. No	Brand	Product	PTR	Sr no in working sheet
1	High D3 1K IU	1000 IU	15.40	Sr no 11 (Annexure 1)
2	Power D3 1K IU	1000 IU	38.50	Sr no 10
3	High D3 60 K IU	60000 IU	84.66	Sr no 28 (Annexure 2)
4	Power D3 60 K IU	60000 IU	84.58	Sr no 29

Since the PTR is similar in 60000 IU strength, they felt that there is anomaly/typographical error in 1000 IU.

Also in the working sheet one more brand viz. D3 Shot of Abbott is not appearing.

Product	Pack Size	Strength	MRP	PTR	MAT August 2015
D3 Shot	10 caps	1000 IU	53.00	40.38	15,11,757

- X. There are some product/brand appearing which are not in existence in market nor are being manufactured and sold by company. They have checked the same from ORG IMS as well as AWACS, and both have confirmed that the packs are incorrectly appearing.
- XI. In respect of **Cefixime Oral Liquid 100 mg/5ml** They tabulate the incorrect entries in the working sheet as follows:

Product	Company	Serial no in working Sheet
ZIPRAX(CIP) 100 MG SYRUP 60 ML	Cipla	8
CEFOLAC 100 MG SYRUP 60 ML	Macleods	17

- XII. In respect of **Cefixime Oral Liquid 50 mg/5ml**, they tabulate the incorrect entries in the working sheet as follows:

Product	Company	Serial no in working Sheet
OMNIX 50 MG SYRUP 50 ML	Cipla	18
MAHACEF 50 MG DRY SYRUP 60 ML	Macleods	50
GRAMOCEF O 50 MG DRY SYRUP 50 ML	Micro Labs	55
C TAX O 50 MG DRY SYRUP 60 ML	Zuventus	73

- XIII. If the aforesaid errors are rectified, the ceiling price in respect of **Cholicalciferol 60 K IU** would work out to **28.70** per capsule, the ceiling price in respect of **Cholicalciferol 1000 IU** would work out to **4.96** per capsule, **Cefixime 200 mg Syrup** would work out to **2.30** per ml and In respect of **Cefixime Oral Liquid 50 mg/5ml** would work out to **1.54** per ml.
- XIV. They requested this Department to look into the matter.

Comments of NPPA:

In this regard, it is stated that:-

(a) Cholicalciferol 60 K IU (Uprise 60 K IU)

- (i) NPPA has fixed ceiling price of Rs. 26.09 per capsule for Cholicalciferol 60 K IU (Uprise 60 K IU), notified vide S.O. 1687(E) dated 09.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on pharmatrac data for August 2015 as per existing practice.
- (ii) The draft-working sheet of revised ceiling price has been uploaded on 20.7.2016 on NPPA's website.

(b) **Cholicalciferol 1000 IU**

- (i) NPPA has fixed ceiling price of Rs. 4.42 per capsule for Cholicalciferol 1000 IU, notified vide S.O. 1687(E) dated 09.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on pharmatrac data for August 2015 as per existing practice.
- (ii) Company's representation is under examination.

(c) **Cefixime Oral Liquid 100mg/5ml (Taxim O Forte Dry Syrup)**

- (i) NPPA has fixed ceiling price of Rs. 1.99 per ml for Cefixime Oral Liquid 100mg/5ml (Taxim O Forte Dry Syrup), notified vide S.O. 1687(E) dated 09.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on pharmatrac data for August 2015 as per existing practice.
- (ii) Company's representation is under examination.

(d) **Cefixime Oral Liquid 50mg/5ml**

- (i) NPPA has fixed ceiling price of Rs. 1.34 per ml for Cefixime Oral Liquid 50mg/5ml, notified vide S.O. 1687(E) dated 09.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on pharmatrac data for August 2015 as per existing practice.
- (ii) Company's representation is under examination.

4. The company was given a personal hearing on 25.7.2016. During the personal hearing, the company as well as NPPA made following further submissions:-

The company representatives confirmed that they have implemented the price notification and submitted Form-V to NPPA. The company representatives made the following further submissions during the hearing –

UPRISE 60 K IU SOFT GELATIN CAPSULE (CHOLICALCIFEROL 60 K IU):

This is a new product covered for the first time in DPCO 2013. Hence this is a price fixation for the first time. Para 16 which covers revision of ceiling price is not applicable. At the start of DPCO in 2013, NPPA had fixed prices for the first time for all new entrants by following para 4, 11 & 14. Now, NPPA has fixed price following para 16. This is a deviation from the policy.

In Schedule I, Cholecalciferol Tablet 60000 IU (S.No.30.4) – Explanation 1 to the note, stated that :-

“To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included”

Thus, above text mentions that if tablet is covered then conventional capsules is also covered and vice versa. NPPA had notified CP of tablets as Rs.23.22/tab vide SO No.1253(E) dated 29.3.2016. Later on NPPA notified CP of capsules as Rs.26.09/cap vide SO No.1687(E), dated 9.5.2016. Alkem product is a soft gelatin capsules. Soft gelatin capsule is different from conventional capsules, hence, the company request NPPA that it should not be covered as per explanation above.

The ceiling price is already notified for capsules (conventional capsules), why the draft working has been put on the website again on 19th July, 2016 including Alkem soft gelatin capsules. The draft working is based on combination of capsule and soft gelatin capsules which is incorrect. If government desires to control soft gelatin capsule, government should first issue or notify that soft gelatin capsule is also covered along with tablet and hard gelatin capsules.

NPPA Representative clarified that ceiling prices are fixed under NLEM 2015 as per the provisions of para 4, 10, 11, 14, 16, 17 & 18 of DPCO 2013 based on the decision of the Authority so as to pass the impact of WPI to manufacturers and consumers. As per the provisions of DPCO 2013, all variant of a formulation will be taken for fixation of ceiling price if not separately mentioned. Draft working sheet dated 19th July, 2016 showing ceiling price fixation in respect of Cholecalciferol Tablet 60000 IU has been made based on the representation made by M/s Alkem Laboratories Ltd. against earlier notification SO 1687(E) dated 09.05.2016 to include their product.

CHOLICALCIFEROL 1000 IU:

This is a new product covered for the first time in DPCO 2013. Hence this is a price fixation for the first time. Para 16 which covers revision of ceiling price is not applicable. At the start of DPCO in 2013, NPPA had fixed prices for the first time for all new entrants by following para 4, 11 & 14. Now, NPPA has fixed price following para 16. This is a deviation from the policy.

In Schedule I, Cholecalciferol Tablet 60000 IU (S.No.30.4) – Explanation 1 to the note, stated that :-

“To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included”

Thus, above text mentions that if tablet is covered then conventional capsules is also covered and vice versa. NPPA notified CP of capsules as Rs.4.42/cap vide SO No.1687(E), dated 9.5.2016. Alkem product is a soft gelatin capsules. Soft gelatin capsule is different from conventional capsules, hence, the company request NPPA that it should not be covered as per explanation above.

In the working sheet, it is observed that there are 2 brands of Unichem viz High D3 & Power D3. There appears to be certain anomaly in the PTR of both the brands. In the working sheet of Choliciferol 60 KIU the PTR are similar but in the working sheet of Choliciferol 1K IU the PTR are different. They hereby presented a tabular view of the same.

Sr. No	Brand	Product	PTR	Sr no in working sheet
1	High D3 1K IU	1000 IU	15.40	Sr no 11 (Annexure 1)
2	Power D3 1K IU	1000 IU	38.50	Sr no 10
3	High D3 60 K IU	60000 IU	84.66	Sr no 28 (Annexure 2)
4	Power D3 60 K IU	60000 IU	84.58	Sr no 29

Since the PTR is similar in 60000 IU strength, they felt that there is anomaly/typographical error in 1000 IU.

Also in the working sheet one more brand viz. D3 Shot of Abbott is not appearing.

Product	Pack Size	Strength	MRP	PTR	MAT August 2015
D3 Shot	10 caps	1000 IU	53.00	40.38	15,11,757

NPPA Representative clarified that ceiling prices are fixed under NLEM 2015 as per the provisions of para 4, 10, 11, 14, 16, 17 & 18 of DPCO 2013 based on the decision of the Authority so as to pass the impact of WPI to manufacturers and consumers. As per the provisions of DPCO 2013, all variant of a formulation will be taken for fixation of ceiling price if not separately mentioned. The matter is under examination based on the representation made by M/s Alkem Laboratories Ltd. on this issue.

TAXIM O FORTE DRY SYRUP (CEFIXIME ORAL LIQUID 100 MG./5 ML):

This is a new product covered for the first time in DPCO 2013. Hence this is a price fixation for the first time. Para 16 which covers revision of ceiling price is not applicable. At the start of DPCO in 2013, NPPA had fixed prices for the first time for all new entrants by following para 4, 11 & 14. Now, NPPA has fixed price following para 16. This is a deviation from the policy.

There are some products/brands appearing which are not in existence in market nor are being manufactured and sold by company. They have checked the same from ORG IMS as well as AWACS, and both have confirmed that the packs are incorrectly appearing.

In respect of **Cefixime Oral Liquid 100 mg/5ml** They tabulate the incorrect entries in the working sheet as follows:

Product	Company	Serial no in working Sheet
ZIPRAX(CIP) 100 MG SYRUP 60 ML	Cipla	8
CEFOLAC 100 MG SYRUP 60 ML	Macleods	17

NPPA Representative clarified that ceiling prices are fixed under NLEM 2015 as per the provisions of para 4, 10, 11, 14, 16, 17 & 18 of DPCO 2013 based on the decision of the Authority so as to pass the impact of WPI to manufacturers and consumers. The matter is under examination based on the representation made by M/s Alkem Laboratories Ltd. on this issue.

CEFIXIME ORAL LIQUID 50 MG/5 ML.:

This is a new product covered for the first time in DPCO 2013. Hence this is a price fixation for the first time. Para 16 which covers revision of ceiling price is not applicable. At the start of DPCO in 2013, NPPA had fixed prices for the first time for all new entrants by following para 4, 11 & 14. Now, NPPA has fixed price following para 16. This is a deviation from the policy.

There are some product/brand appearing which are not in existence in market nor are being manufactured and sold by company. They have checked the same from ORG IMS as well as AWACS, and both have confirmed that the packs are incorrectly appearing.

In respect of **Cefixime Oral Liquid 50 mg/5ml**, they tabulate the incorrect entries in the working sheet as follows:

Product	Company	Serial no in working Sheet
OMNIX 50 MG SYRUP 50 ML	Cipla	18
MAHACEF 50 MG DRY SYRUP 60 ML	Macleods	50
GRAMOCEF O 50 MG DRY SYRUP 50 ML	Micro Labs	55
C TAX O 50 MG DRY SYRUP 60 ML	Zuventus	73

NPPA Representative clarified that ceiling prices are fixed under NLEM 2015 as per the provisions of para 4, 10, 11, 14, 16, 17 & 18 of DPCO 2013 based on the decision of the Authority so as to pass the impact of WPI to manufacturers and consumers. The matter is under examination based on the representation made by M/s Alkem Laboratories Ltd. on this issue.

4. Examination:

The petitioner company has challenged the Order No. SO No.1687(E) dated 09.05.2016 for price fixation of “Uprise 60K IU Soft Gelatin Capsule (Cholicalciferol 60K IU), Cholicalciferol 1000 IU, Taxim O Forte Dry Syrup (Cefixime Oral Liquid 100mg./5ml and Cefixime Oral Liquid 50mg/5ml” under DPCO, 2013.

The petitioner company has raised the following points:

- (i) NPPA has fixed the ceiling price of their products vide SO No.1687(E) dated 09.05.2016 using Para 16(i) which is applicable in case of existing products and not for their products that have been included in schedule list.
- (ii) NPPA has not taken into account the correct PTR and MAT for fixation of the price of the afore-mentioned products which needs to be corrected by NPPA.

As regards point (i) above, it is seen that the impact of WPI should be taken into consideration in case of revision of prices under Para 16(1), which reads as under::

“The Government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year.”

As this is a case, where the product is being included in Schedule-I medicine list of DPCO, 2013 for the first time, Para 9(5) (instead of Para 16) is applicable, which reads as under:-

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule.”

As such NPPA may be directed to consider re-fixation of prices of medicines that have become scheduled for the 1st time due to their inclusion in revised schedule-I of DPCO, 2013 in light of Para 4 and Para 9(5) of DPCO, 2013.

In regard to point (ii) NPPA has mentioned that the matter is under examination based on the representation made by M/s Alkem Laboratories Ltd. NPPA may be asked to examine the data/information furnished by the petitioner company and re-fix the price of the products of the petitioner company.

5. **Government decision:**

NPPA shall re-fix and re-notify the price of the products of the petitioner company under Para 4, taking into account Para 9(5) of DPCO, 2013. Para 16(1) will not be applicable here.

NPPA is also directed to examine any relevant data furnished by the petitioner company on merits and to re-fix the ceiling price of their products under review within one month of the decision in this regard.

In view of the above, the present review petition stands disposed off.

Issued on this date, the 14th day of September, 2016.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

- 1. M/s. Alkem Laboratories Ltd.
Alkem House, Senapati Bapat Marg,
Lower Parel, Mumbai-400 013.**
- 2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**