

No. 31015/54/2016-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 Abbott Healthcare Pvt. Limited against price fixation of “Ascorbic Acid (Vitamin C) Tablet-500 mg” vide NPPA order No. S.O. 1351(E) dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 16.06.2016
2) NPPA notification under review S.O. No.1351(E) dated 02.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 28.7.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott Healthcare Pvt. Limited (hereinafter called the petitioner) against notification S.O. No.1351(E) dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ascorbic Acid (Vitamin C) Tablet-500 mg.

2. The petitioner has contended as under:

I. While reviewing the working sheet uploaded on the NPPA webpage, they have come across the below discrepancies resulting in an incorrect reduction in the ceiling price:

- Celin 500 MG Tablet – Pack size 50 has been included in working, which is not in circulation in market and is INACTIVE as per AWACS database to which they also subscribe.
- Celin 500 MG Tablet – Pack size 10 has been included in working, which is not in circulation in market and is INACTIVE as per AWACS database to which they also subscribe.
- Celin Chew 500 MG Tablet – Pack size 20 is the Active Pack which has been included in NPPA working but the PTR mentioned of 14.08 for 20s tablet is incorrect . The subject PTR 14.08 captured from AWACS database quotes MRP as 17.45 however the correct MRP is 20.47 for 20s tablet and hence PTR has to be 16.50 per strip of 20s tablet.
- The average pricing formula has included Plain Tablet (Celin 500mg) and Chewable Table (Limcee 500 mg and Celin Chewable 500 mg) in the same basket despite the fact that the Plain tablet has formulation content “Ascorbic Acid” whereas Chewable Tablet has formulation content of “Ascorbic Acid and Sodium Ascorbate”.

II. Chewable tablets have a better acceptance compared to other dosage forms of Vitamin C supplements. Chewable tablets have a smooth texture upon disintegration, are pleasant tasting and leave no bitter or unpleasant taste.

Geriatric and pediatric patients and travelling patients who may not have ready access to water are most need of easy swallowing dosage forms like chewable tablets. **Chewable tablet have improved patient acceptance (especially pediatric) through pleasant taste.**

- III. The Average Pricing Formula needed to be applied separately for the Chewable tablets basket (Abbott - Limcee Chewable Tablets and GSK - Celin Chewable Tablets)
- IV. The reduction has led to a significant reduction in MRP for their Vitamin drug – Limcee chewable tablets which was already a price controlled formulation under DPCO'95 and has been witnessing soaring API prices. However being a market leader in this Vitamin category they had continued to manufacture for serving the patient needs as a responsible healthcare company and had been requesting for compensation towards API price increases. This reduction has come as a big blow for maintaining continuity of manufacturing operations
- V. **Hence they requested this Department to urgently correct the PTRs and revise the working considering the negative impact due to an incorrect working methodology. As per review filing guidelines, they have implemented the ceiling price** and have started sticker the inventory in hand with the revised notified MRPs for our SKU Limcee Chewable Tablet – 500mg

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.73 per tablet for Ascorbic Acid (Vitamin C) tablet- 500 mg vide S.O. 1351(E) dated 02/06/2016 under para 4,10,11,14,16,17 & 18 of DPCO, 2013 based on the data provided by pharma-trac for August, 2015.
- (ii) Company's representation is under examination.
- (iii) There is no provision in DPCO, 2013 for compensation towards API price increases.

3. During the personal hearing held on 28.7.2016, the company representatives confirmed that they have adhered to the price notified vide SO 1351(E), dated 2.6.2016 before filing the review application and furnished Form-V to the effect. The company representatives further submitted that –

- I. **Under DPCO 1995,NPPA vide S.O. 1617(E) dated 19th July 2012 had notified the prices for Vitamin C, but categorically specified different prices for**
 - A. Plain Vitamin C tablet
 - B. SR/DR/CR/Long acting tablet
 - C. Chewable tablet
 - D. Film coated tablet
 - E. Capsule
- II. While DPCO 2013 elaborates that if a tablet is included, other dosage forms like conventional tablets & capsules are also considered as included. **However such**

different dosage forms should be considered differently for purpose such as pricing. This principle applies to all other dosage form i.e. eg. Oral liquid dosage forms, injectable, topical dosage forms

- III. **Innovation** in medicine must be encouraged & hence such different formulations/dosage form (Oral Chewable, Oral mouth dissolving) should be **considered differently for purposes of pricing.**
- IV. Celin 500 MG Tablet – Pack size 50 has been included in working , which is not in circulation in market and is **INACTIVE as per AWACS** database to which we also subscribe
- V. Celin Chew 500 MG Tablet – Pack size 20 is the Active Pack which has been included in NPPA working but the **PTR mentioned of 14.08 for 20s tablet is incorrect** . The subject PTR 14.08 captured from AWACS database quotes MRP as 17.45 however the correct MRP is 20.47 for 20s tablet and hence PTR has to be 16.50 per strip of 20s tablet
- VI. The average pricing formula has included Plain Tablet (Celin 500mg) and Chewable Table (Limcee 500 mg and Celin Chewable 500 mg) in the same basket despite the fact that the **Plain tablet has formulation content “Ascorbic Acid” whereas Chewable Tablet has formulation content of “Ascorbic Acid and Sodium Ascorbate”**
- VII. Chewable tablets have a better acceptance compared to other dosage forms of Vitamin C supplements. Chewable tablets have a smooth texture upon disintegration, are pleasant tasting and leave no bitter or unpleasant taste. Geriatric and pediatric patients and travelling patients who may not have ready access to water are most need of easy swallowing dosage forms like chewable tablets. **Chewable tablet have improved patient acceptance (especially pediatric) through pleasant taste**
- VIII. **The Average Pricing Formula needed to be applied separately** for the Chewable tablets basket segment Company Abbott - Limcee Chewable Tablets and GSK - Celin Chewable Tablets.
- IX. The recent reduction has led to a significant reduction in MRP for our Vitamin drug – Limcee chewable tablets which was already a price controlled formulation under DPCO'95 and has been **witnessing soaring API prices**. However being a market leader in this Vitamin category we had continued to manufacture for serving the patient needs as a responsible healthcare company and had been requesting for compensation towards API price increases. This reduction has come as a big blow for maintaining continuity of manufacturing operations.

The company representative once again requested for correction of the already notified ceiling price at the earliest, since they continue to undertake production, despite making losses post the 2nd June, 2016 price notification.

NPPA representative submitted that there is no provision in DPCO 2013 for fixing separate ceiling price for Vitamin C 500 mg tablet and Vitamin C Chewable tablet.

Further, DPCO 2013 does not provide for passing on the impact of API prices. NPPA is examining this issue based on the representation submitted by the company.

4. **Examination:**

The petitioner company has challenged the NPPA Order No.S.O. 1351(E) dated 02.06.2016 (page 7/cor) for price fixation of "Ascorbic Acid (Vitamin C) Tablet -500mg". The main contentions of the petitioner company are as under:

- I. The following discrepancies have been noticed in the working sheet:-
 - (i) Celin 500mg Tablet – Pack size 50 has been included in working, which is not in circulation in market and is INACTIVE as per AWACS database to which they also subscribe.
 - (ii) Celin 500mg Tablet – Pack size 10 has been included in working, which is not in circulation in market and is INACTIVE as per AWACS database to which they also subscribe.
 - (iii) Celin Chew 500mg Tablet – Pack size 20 is the Active Pack which has been included in NPPA working but the PTR mentioned of 14.08 for 20s tablet is incorrect. The subject PTR 14.08 captured from AWACS database quotes MRP as 17.45 however, the correct MRP is 20.47 for 20s tablet and hence PTR has to be 16.50 per strip of 20s tablet.
 - (iv) The average pricing formula has included Plain Tablet (Celin 500mg) and Chewable Tablet (Limcee 50mg and Celin Chewable 500mg) in the same basket despite the fact that the Plain tablet has formulation content "Ascorbic Acid" whereas Chewable Tablet has formulation content of "Ascorbic Acid and Sodium Ascorbate".

II. The petitioner company has brought to the notice that their product i.e. Limcee 500mg is a chewable Vitamin C Tablet. The chewable Tablets have a better acceptance compared to other dosage forms of Vitamin C supplements. Chewable tablets have a smooth texture upon disintegration, are pleasant tasting and leave no bitter or unpleasant taste. Geriatric and pediatric patients and travelling patients who may not have ready access to water are most need of easy swallowing dosage forms like chewable tablets. **Chewable tablet have improved patient acceptance (especially pediatric) through pleasant taste.**

With respect of point (i) above NPPA has informed that the representation of the petitioner company in this regard is already under examination with them. We may request NPPA to consider the data/information provided by the petitioner company on merits and re-fix the ceiling price of the product immediately.

Regarding Point (ii) above NPPA has informed that there is no provision in the DPCO, 2013 for fixing separate ceiling price for Vitamin C 500mg tablet and Vitamin C Chewable tablet.

The stand of the NPPA seems to be in line with the provisions of DPCO 2013 as it does not distinguish between Vitamin C (Ascorbic Acid) plain and chewable tablets.

Also there is no specific therapeutic rational for considering the product for separate pricing.

5. **Government Decision:**

Any relevant data/information furnished by the petitioner company may be examined by NPPA on merit and to re-fix the price of the product of the petitioner company within one month of the decision in this regard.

As regards request of the petitioner for considering their product, i.e. Vitamin C Chewable Tablet, for separate pricing, the same is rejected.

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. Abbott Healthcare Pvt. Limited,
D Mart Building,
Goregaon Mulund Link Road,
Mulund West, Mumbai-400 080.**
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**