

**No. 31015/37/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Three Review applications of M/s Abbott Healthcare Pvt. Limited against price fixation of their formulations “Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg + 40mg/5ml; Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg + 160mg and Phenobarbitone - 20mg/5ml” vide NPPA order No. S.O. 443(E), dated 14.2.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Three Review applications dated 09.03.2017
2) NPPA notification under review S.O. No.443(E), dated 14.2.2017
3) Record Note of discussions held in the personal hearing on 23.5.2017.

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.443(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg + 40mg/5ml; Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg + 160mg and Phenobarbitone - 20mg/5ml.

2. The petitioner has contended as under:

In respect of Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 200mg+40mg/5ml:-

- (i) They had already made their review petition representation dated 03.11.2016 to NPPA, wherein they have mentioned that the draft working sheet for ceiling price calculation of **Co-trimoxazole [Sulphamethoxazole + Trimethoprim]-200mg + 40mg/5ml** (vide8(35)/2016/DP/NPPA/Div II dated 26.10.2016) were bearing anomaly in calculation .
- (ii) NPPA has considered PTR Rs. 0.10 and Rs. 0.17 per ml for Septran pediatric suspension 100ml & 60ml of Glaxosmithkline Pharmaceutical Ltd., whereas they understand from IMS data that these two packs are discontinued. They are currently marketing Septran pediatric suspension 50ml pack.

In respect of Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 800mg+160mg:-

- (i) NPPA has not considered **PTR** of our Product Bactrim DS Tablet 10's for the purpose of calculation of Ceiling Price.

- (ii) Their product Bactrim DS Tablet 10's **PTR is INR 11.06** (INR 1.11 per tablet) and **MAT Aug'15 value is INR 12.27 crs which is as per AWACS dataset.**
- (iii) NPPA has considered PTR INR 0.55 for Septran DS 800/160mg Tablet 10's of M/s Glaxosmithkline Pharmaceutical Ltd. which is not correct. The Correct PTR is INR 11.72 (INR 1.17 per tablet) which is as per AWACS dataset.

In respect of Phenobarbitone – 20mg/5ml:-

- (i) Company submitted that, while the Mat Aug'15 PTR is being used for ceiling price calculation, **however NPPA may need to refer the ceiling price notification no. S.O. 582(E) dated 24.02.2016 & S.O. 644 (E) dated 02.03.2016 vide which the upward revision of ceiling price for Phenobarbitone syrup was awarded after a long wait,** since the previous notification SO 619(E) dated 24.02.2015 had calculation errors which finally got corrected by NPPA in Mar'16.
- (ii) Hence referring to MAT Aug'15 PTR will be an anomaly since the earlier ceiling Price (S.O. 619(E) dated 26.02.15 had been challenged by Abbott vide review hearing and NPPA had finally revised the price upward after acknowledging the errors in calculation methodology.
- (iii) **The applicable PTR for Phenobarbitone oral liquid 20mg/5ml should be of March '16 and not Aug'15 as revised price was notified in March'16.**

They appealed to the authority to advise NPPA to correct the apparent variance in calculation.

3. Comments of NPPA:

- I. In this regard, it is mentioned that ceiling price of Rs. 0.20/ml for **Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg+40mg/5ml Suspension**, Rs. 0.98/tablet for **Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg+160mg Tablet** and Rs. 0.35/ml for **Phenobarbitone Oral Liquid 20mg/5ml** was notified vide S.O. 443(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg+40mg/5ml Suspension, Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg+160mg Tablet and Phenobarbitone Oral Liquid 20mg/5ml.** The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
(i) Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg+40mg/5ml Suspension:-		
1.	Company has stated that they have submitted representation against Draft working sheet and	NPPA examined the representation submitted by

	the same was not considered by NPPA.	the company but the representations being not conclusively proved hence rejected.
2.	Company has pointed out that NPPA has considered PTR of Rs. 0.10 & Rs. 0.17 for Septran Pediatric suspension 100ml & 60ml respectively of M/s GlaxoSmithkline Pharmaceuticals Ltd. those are not available in the market.	NPPA has considered the PTR of Rs. 0.10 & Rs. 0.17 for Septran Pediatric suspension 100ml & 60ml respectively of M/s GlaxoSmithkline Pharmaceuticals Ltd. as per data provided by PharmaTrac for the period of August, 2015. M/s GlaxoSmithkline Pharmaceutical Ltd. has not raised any objection regarding inclusion of these packs in calculation sheet.
(ii) Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg+160mg Tablet		
1.	Company has pointed out that NPPA has not considered PTR of Rs. 11.06 for their product Bactrim-DS tablet in calculation sheet for deriving the ceiling price.	NPPA has considered the PTR of Rs. 0.55 for Septran-DS 800/160mg tablet of M/s GlaxoSmithkline Pharmaceuticals Ltd. as per data provided by PharmaTrac for the period of August, 2015. The representation submitted by M/s Abbott Healthcare Pvt. Ltd. & M/s GlaxoSmithkline Pharmaceutical Ltd. was examined by NPPA but based on documents and evidences provided by companies the representation was not conclusively proved, hence rejected.
2.	NPPA has considered the PTR of Rs. 0.55/tablet against actual PTR of Rs. 1.17/tablet for Septran 800mg & 160mg for M/s GlaxoSmithkline Pharmaceuticals Ltd.	NPPA considered the PTR of Rs. 0.55/tablet for Septran 800mg & 160mg for M/s GlaxoSmithkline Pharmaceuticals Ltd as per data provided by PharmaTrac for the period of August, 2015

(iii) Phenobarbitone Oral Liquid 20mg/5ml		
1.	Company requested NPPA to consider PTR for the period of March, 2016 against August, 2015 as Phenobarbitone price was revised by S.O. 582(E) dated 24.02.2016.	NPPA has rightly considered the PTR as provided by pharma-trac for the period of August, 2015 as per existing practice.

III. Company has not challenged any notification in respect of **Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg+40mg/5ml Suspension, Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg+160mg Tablet and Phenobarbitone Oral Liquid 20mg/5ml** in the Court.

4. During the personal hearing, the representatives of the company further submitted the following submissions in respect of –

Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 200mg+40mg/5ml:

IMS data reconciled with Pharmatrac data has led the company to believe that GSK's brand Septran pediatric suspension 100 ml & 60 ml have been discontinued and price should be revised by excluding the discontinued brands of GSK.

Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 800mg+160mg:

Abbott's brand Bactrim tablet 10's having a PTR of Rs.11.06 with MAT value Rs.12.27 crs. as per Pharmatrac data should be considered and re-fix the ceiling price. Documentary proof of the same in the form of verification from Pharmatrac was submitted.

NPPA has considered PTR Rs.5.53 per 10's pack of GSK's brand Septran DS 800/160 mg whereas the correct PTR is Rs.11.72 for 10's pack. Documentary proof of the same in the form of verification from Pharmatrac was submitted.

Phenobarbitone – 20mg/5ml.

The ceiling price of Phenobarbitone syrup should be re-fixed as in line with NPPA SO No.582(E), dated 24.2.2016.

The company representatives also pointed out the recent ceiling price notification by NPPA with respect to Phenobarbitone 30mg tablet fixed vide SO 1569(E), dated 15.5.2017 based on DoP Review Order No.31015/71/2016-PI.I, dated 30.1.2017. The company representatives submitted that the same principle should be applied in the instant case.

The NPPA representatives stated that the documents submitted by the company for revision of ceiling prices of Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 200mg+40mg/5ml Suspension, Co-trimoxazole (Sulphamethoxazole + Trimethoprim) - 800mg+160mg Tablet and Phenobarbitone Syrup may be examined.

5. **Examination:**

Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 200mg+40mg/5ml:-

The petitioner company submitted that they understand from IMS data that the two packs of Glaxosmithkline Pharmaceuticals Ltd., viz. Septran pediatric suspension 100ml & 60ml are discontinued. Company has not submitted any concrete proof in support of their claim. NPPA has considered the Pharmatrac data, as per existing practice for fixing ceiling price. **Hence, there is no merit in the grievance of the petitioner company and may not be considered.**

Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 800mg+160mg:-

In support of their claim, the petitioner company has submitted the data arranged from Pharmatrac (page 33/c). On seeing the statement, it is seen that the claim of the petitioner company that PTR of their Product Bactrim DS Tablet 10's has not been considered for the purpose of calculation of Ceiling Price, although their product Bactrim DS Tablet 10's PTR is Rs.11.06 (Rs.1.11 per tablet) and MAT Aug'15 value is Rs.12.27 crs. Pharmatrac confirmed that this product was not considered being of different strength. **Therefore, the claim of the petitioner company has got no merit and deserves to be rejected.**

As regards the claim of the petitioner company that the correct PTR of Septran DS 800/160mg tablet for 10's pack is Rs.11.72 (Rs.1.17 per tablet), being manufactured by M/s Glaxosmithklin Pharmaceuticals Ltd. **can be considered by NPPA after getting confirmation from Pharmatrac**, since the documentary proof of Pharmatrac data, submitted by the petitioner company, supports the claim of the company.

Phenobarbitone – 20mg/5ml:-

The company challenged the price calculation for Phenobarbitone – 20mg/5ml. Company submitted that NPPA considered Aug'15 PTR for ceiling price calculation. However, upward revision of ceiling price for Phenobarbitone syrup was awarded by NPPA vide S.O. 582(E) dated 24.02.2016 & S.O. 644 (E) dated 02.03.2016, where the ceiling price of Phenobarbitone Syrup 20mg was fixed as Rs.0.56/ml and Rs.0.54/ml (after giving WPI impact) respectively. The notification SO 582(E), dt.24.2.2016 is placed at page 44-45/c and SO 644(E), dt.2.3.2016 is at page 46-58/c (price of formulation is at S.No.410, p.49/c). **The company's grievance that considering August, 2015 data and ignoring February/March, 2016 data, while fixing the ceiling price, has got merit and deserves consideration.**

6. **Government Decision:**

"The grievance of the petitioner company that while fixing the ceiling price of Co-trimoxazole [Sulphamethoxazole+Trimethoprim]- 200mg+40mg/5ml, NPPA considered two packs of Glaxosmithkline Pharmaceuticals Ltd., viz. Septran pediatric suspension 100ml & 60ml which are discontinued, has got no merit and stands rejected, as NPPA rightly considered Pharmatrac data.

The claim of petitioner company about not including the PTR of their Product Bactrim DS Tablet 10's for fixing the Ceiling Price of Co-trimoxazole [Sulphamethoxazole+ Trimethoprim]- 800mg+160mg, cannot be considered, being their product of different strength, and stands rejected. However, NPPA is directed to examine the information/ documentary proof about correct PTR of Septran DS 800/160mg tablet (Rs.1.17/tablet), being manufactured by M/s Glaxosmithklin Pharmaceuticals Ltd., and revise/refix the ceiling price of the formulation, on merit.

NPPA is also directed to refix the ceiling price of Phenobarbitone-20mg/5ml by using the corrected price of the petitioner company prevalent in August, 2015 after due revision and correction of the ceiling price by NPPA in February/March, 2016.”

Issued on this date of 28th day of September, 2017.

(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