

No. 31015/90/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A wing, Shastri Bhavan
New Delhi 110 001

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO,2013

Subject: Review application of M/s Sun Pharmaceutical Industries Limited against NPPA S.O. No. 2963(E) dated 15/09/2016 for Price fixation of six formulations (Methotrexate Tablet 5 mg, Levodopa 250 mg + Carbidopa 25 mg Tablet, Hydrochlorothiazide Tablet 12.5 mg, Hydrochlorothiazide Tablet 25 mg, Carbamazepine Tablet 100 mg, Sodium Valproate 100 mg/ml injection) and against S.O No. 2964(E) dated 15/9/16 for Price fixation of Cholecalciferol (Vitamin D3) 60000 IU Capsule, both issued under Drugs (Prices Control) Order, 2013.

Ref: (1) Review application dated 14/10/2016
(2) NPPA notification under review S.O No. 2963(E) dated 15/09/2016
(3) NPPA notification under review S.O No. 2964(E) dated 15/09/2016

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. 2963(E) dated 15/09/2016 for Price fixation of six formulations (Methotrexate Tablet 5 mg, Levodopa 250 mg + Carbidopa 25 mg Tablet, Hydrochlorothiazide Tablet 12.5 mg, Hydrochlorothiazide Tablet 25 mg, Carbamazepine Tablet 100 mg, Sodium Valproate 100 mg/ml injection) and S.O No. 2964(E) dated 15/9/16 for price fixation of Cholecalciferol (Vitamin D3) 60000 IU Capsule, both issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA).

2. **The petitioner has contended as under:**

(a) While fixing the ceiling price for above mentioned six formulations, notified vide S O No. 2963(E) dated 15.9.2016, NPPA has not considered actual PTR applicable in the month of August 2015 and have ignored the representations submitted by the Company on this issue. This in turn has led to the fixation of the ceiling price of the above mentioned six formulations based on incorrect PTR data, which is not as per the provision of DPCO 2013.

(b) NPPA has notified the ceiling price of this Cholecalciferol (Vitamin D3) 60000 IU Capsule via S.O. No. 2964(E) dated 15.09.2016 without including two of their product packs namely NeuroD3 60K, and D-Well aq in this formulation category. These 2 product packs were launched after August 2015 and as per

para 9(2) of DPCO 2013 these packs should have been considered in ceiling price calculation of Cholecalciferol 60000 IU Capsules.

(c) NPPA has wrongly included pack of D WELL CHEW 60000 IU TABLET 4 while fixing the ceiling price.

3. Comments of NPPA

NPPA has fixed the following ceiling prices in respect of above mentioned formulations as given in the table below:-

Medicines	Route of Administration/ Dosage Form	Strength	Unit	Ceiling Price (Rs.)	Reason for increase/decrease	S.O. No.	Date of Notification	Remarks
Methotrexate	Tablets	5mg	tablet	Rs. 7.60		S.O. 1561(E)	14.06.2013	NLEM 2011
				Rs. 8.08	Impact of WPI	S.O. 1156(E)	28.04.2014	NLEM 2011
				Rs. 8.39	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 8.16	Impact of WPI	S.O. 644(E)	2.03.2016	NLEM 2011
				Rs. 7.45		S.O. 2963(E)	15.09.2016	NLEM 2015
Levodopa + Carbidopa	Tablets	250mg + 25mg	tablet	Rs. 3.46		S.O. 951(E)	27.03.2014	NLEM 2015
				Rs. 3.85	Representation by the Companies	S.O. 2095(E)	20.08.2014	NLEM 2015
				Rs. 4.00	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2015
				Rs. 3.89		S.O. 644(E)	02.03.2016	NLEM 2015
				Rs. 3.46		S.O. 2963(E)	15.09.2016	NLEM 2015
Hydrochlorothiazide	Tablets	12.5mg	tablet	Rs. 0.97		S.O. 1639(E)	14.06.2013	NLEM 2011
				Rs. 1.03	Impact of WPI	S.O. 1156(E)	28.04.2014	NLEM 2011
				Rs. 1.07	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 1.04	Impact of WPI	S.O. 644(E)	02.03.2016	NLEM 2011
				Rs. 0.91		S.O. 2963(E)	15.09.2016	NLEM 2015

Hydrochlorothiazide	Tablets	25mg	tablet	Rs. 1.66		S.O. 1640(E)	14.06.2013	NLEM 2011
				Rs. 1.76	Impact of WPI	S.O. 1156(E)	28.04.2014	NLEM 2011
				Rs. 1.83	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 1.78	Impact of WPI	S.O. 644(E)	02.03.2016	NLEM 2011
				Rs. 1.57		S.O. 2963(E)	15.09.2016	NLEM 2015
Carbamazepine	Tablets	100mg	tablets	Rs. 0.70		S.O. 1010(E)	02.04.2014	NLEM 2011
				Rs. 0.74	Impact of WPI	S.O. 2095(E)	20.08.2014	NLEM 2011
				Rs. 0.77	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 0.75	Impact of WPI	S.O. 644(E)	02.03.2016	NLEM 2011
				Rs. 0.64		S.O. 2963(E)	15.09.2016	NLEM 2015
Sodium Valproate 100mg/ml	Injection	100mg/ml	Injection	Rs. 5.39/ml		S.O. 1880(E)	28.06.2013	NLEM 2011
				Rs. 5.73/ml	Impact of WPI	S.O. 1156(E)	28.04.2014	NLEM 2011
				Rs. 5.95/ml	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 5.79/ml	Impact of WPI	S.O. 644(E)	02.03.2016	NLEM 2011
				Rs. 5.34/ml		S.O. 2963(E)	15.09.2016	NLEM 2015
Mifepristone	Tablets	200mg	tablet	Rs. 357.13		S.O. 2254(E)	22.07.2013	NLEM 2011
				Rs. 379.70	Impact of WPI	S.O. 1156(E)	28.04.2014	NLEM 2011
				Rs. 394.31	Impact of WPI	S.O. 619(E)	26.02.2015	NLEM 2011
				Rs. 383.62	Impact of WPI	S.O. 644(E)	02.03.2016	NLEM 2011
				Rs. 298.49		S.O. 1819(E)	18.05.2016	NLEM 2015
Cholecalciferol (Vitamin D3)	Capsules	60000IU	Capsule	Rs. 27.40		S.O. 2964(E)	15.09.2016	NLEM 2015

Cholecalciferol (Vitamin D3)	Tablets	60000IU	tablet	Rs. 22.50		S.O. 2964E)	15.09.2016	NLEM 2015
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It is to be noted that negative WPI was prevalent in Aug. 2015, which is the reference date i.e. six months prior to date of notification of revision of Schedule-1 (i.e. 10.03.2016) as per Para 9(5) of DPCO 2013. This practice has been followed uniformly.

5. Examination:

The petitioner company in its review application submitted that they have represented encompassing necessary documents claiming that in case of 5 formulations, PTR as mentioned in the draft working sheet is different from the actual PTR. However, NPPA notified SO 2963(E), without giving any consideration to their representation.

Similarly, NPPA notified SO 2964(E) without giving due merit consideration to their representation, wherein the company submitted that their two product packs namely NeuroD3 60K and D-Well aq have not been included in the ceiling price calculation. Also the PTR of product pack ENCORATE 100 MG INJECTION 5 ML is different from the actual PTR.

Keeping in view the representations submitted documents submitted along with the supporting documents, NPPA may be directed to examine the documents submitted by the petitioner company on merit, and re-fix/revise the price of the subject formulations, if necessary.

7. Decision of the Government:

“NPPA is hereby directed to examine the documents submitted by the petitioner company on merit and to re-fix/revise the price of the formulations, as necessary”.

Issued on this date, the 10th day of March, 2017.

(Jai Priye Prakash)
Secretary
For and on behalf of the President of India

To

1. Sun Pharmaceutical Industries Ltd
8-C, 8th Floor, Hansalya Building,
15, Barakhamba Road, Conaught Place,
New Delhi-110001
INDIA.

2. The Member Secretary
National Pharmaceutical Pricing Authority
YMCA Cultural Centre Building
New Delhi – 110 001.

Copy to:

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