

**No. 31015/39/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

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A- Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Two Review applications of M/s Sun Pharma Laboratories Limited against price fixation of “Adenosine 3mg/ml Injection, Isosorbide -5-Mononitrate 10mg tablet and Isosorbide -5-Mononitrate 20mg tablet” vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Two Review applications dated 09.03.2017  
2) NPPA notification under review S.O. 443(E), dated 14.02.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 27.06.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Adenosine 3mg/ml Injection, Isosorbide -5- Mononitrate 10mg tablet and Isosorbide -5-Mononitrate 20mg tablet.

2. The petitioner has contended as under:-

**I. In respect of Adenosine 3 mg/ml Injection**

Working sheet of Adenosine 3 mg/ml Injection notified under NPPA S.O. No. 443(E) dated 14.02.2017 captured only 2 packs. **Their 2 product packs viz. ADENOJECT 10 ML INJECTION 1, and ADENOJECT 2ML INJECTION 1 erroneously been missed out in the ceiling price calculation.** As these 2 product packs are having same strength of Adeosine 3 mg/ml, hence both of these packs should be included in ceiling price calculation.

**II. In respect of Isosorbide-5-Mononitrate 10 mg tablets and 20 mg tablets**

(i) Draft working sheet of 18 formulations including captioned formulations was displayed on NPPA website on 21.10.2016. Displayed draft working sheet captured Price To Retailer (PTR) as Rs. 16.50 for Isosorbide-5-Mononitrate 10 mg Tablets, and Rs. 28.28 Isosorbide-5-Mononitrate 20 mg Tablets, which is different from the actual August 2015 PTR, as Rs. 17.11, and Rs. 29.30 respectively. They had submitted their representation dated 02.11.2016 along with necessary documents within 10 working days of draft working sheet presentation on NPPA website.

(ii) Company had received a letter dated 16.11.2016 (Ref: F. No. 7(60)/2016/DP/NPPA/Div. II) from NPPA for submitting the additional details for the month of August 2015, within 7 days (by 23.11.2016), which company had duly submitted through their letter dated 22.11.2016.

(iii) Ceiling price of captioned formulations were notified via S.O. No. 443 (E) dated 14.02.2017 **without considering their representation, and submission.**

2.2 In view of the above, company requested this Department to issue necessary directives to NPPA to re-notify the ceiling price of the above said formulations.

3. **Comments of NPPA:**

In this regard, it is mentioned that ceiling price of **Adenosine 3mg/ml Injection** was notified as Rs. 82.75/ml vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 84.38/ml vide S.O. 1039(E) dated 01.04.2017, **Isosorbide -5- Mononitrate 10mg tablet** was notified as Rs. 1.82/tablet vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 1.84/tablet vide S.O. 1039(E) dated 01.04.2017 and **Isosorbide -5- Mononitrate 20mg tablet** was notified as Rs. 2.84/tablet vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 2.90/tablet vide S.O. 1039(E) dated 01.04.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of **Adenosine 3mg/ml Injection, Isosorbide -5- Mononitrate 10mg tablet and Isosorbide -5-Mononitrate 20mg tablet**. 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
1.	<b>Adenosine 3mg/ml Injection:-</b>	
	Company has pointed out that their two products viz. Adenoject 10ml Injection 1 and Adenoject 2ml Injection 1 have not been included in calculation sheet for calculating the ceiling price for Adenosine 3mg/ml Injection.	NPPA considered the data provided by AIOCD-AWACS for the month of August, 2015. DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: <i>"NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after</i>

		<p><i>taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals &amp; Fertilizers)".</i></p> <p>Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days.</p> <p><b>M/s Sun Pharma laboratories Ltd. <u>did not make any representation against the proposed retail price uploaded on NPPA's website.</u></b></p>
2	<b>Isosorbide -5- Mononitrate 10mg &amp; 20mg tablet:-</b>	
	<p>Company has stated that NPPA has considered Rs. 16.50/tablet as PTR against the actual PTR as Rs. 17.11 and Rs. 28.28 for Isosorbide -5-Mononitrate 10mg tablet. Company has also pointed out that they had submitted the representation on 02.11.2016 against the draft working sheet and also submitted additional details vide letter dated 22.11.2016 for the month of August, 2015.</p>	<p>NPPA considered the data provided by AIOCD-AWACS for the month of August, 2015. NPPA examined the representation and additional data but the same was not considered by the authority as AIOCD-AWACS has not confirmed the company's claim.</p>
		<p><b>Detail of trade margin based on AIOCD-AWACS data as on August 2015:-</b></p> <p>Trade Margin from PTS level of:-  Adenoject 2ml-61.65%  Adenoject 10ml-49.61%  Isosorbide 5 Mononitrate 10mg tablet – not reflected in AIOCD-AWACS data  Isosorbide 5 Mononitrate 20mg tablet – not reflected in AIOCD-AWACS data</p>

3.3 Company has not challenged any notification in respect of **Adenosine 3mg/ml Injection, Isosorbide -5- Mononitrate 10mg tablet and Isosorbide -5-Mononitrate 20mg tablet** in the Court.

4. During the personal hearing, the representatives of the company made following further submissions –

### **Adenosine 3 mg/ml Injection**

1. Working sheet of Adenosine 3 mg/ml Injection notified under NPPA S.O. No. 443(E) dated 14.02.2017 captured 2 packs in totality. However, other products including two of the company's products, viz. ADENOJECT 10 ML INJECTION 1, and ADENOJECT 2ML INJECTION 1 have been missed out in the ceiling price calculation.
2. Company has also submitted copies of both the product packs as mentioned above during the personal hearing and requested to include both the packs in the ceiling price calculation.
3. Company has already submitted copy of Price List in Form V of DPCO 2013 of ADENOJECT 10 ML INJECTION 1, and ADENOJECT 2ML INJECTION 1 along with review application.
4. For the comments given by NPPA in the brief of hearing about detail of trade margin based on AIOCD-AWACS data as on August, 2015, the company representative submitted that they are giving margin to retailers and wholesalers as per the existing standard trade practice prevalent in the pharmaceutical industry.

### **Isosorbide-5-Mononitrate 10mg tablets and 20mg tablets**

1. Company had represented against draft working sheet of these two formulations dated 2<sup>nd</sup> November, 2016 and further, submitted additional details vide their letter dated 22<sup>nd</sup> November, 2016, in response to NPPA's letter dated 16.11.2016 (Ref: F. No. 7(60)/2016/DP/NPPA/Div. II).
2. However, Ceiling price of captioned formulations were notified via S.O. No. 443(E) dated 14.02.2017 without considering our representation, and additional submission.
3. For the comment of NPPA in the brief of personal hearing stating that "NPPA considered the data provided by AIOCD-AWACS for the month of August, 2015. NPPA examined the representation and additional data but the same was not considered by the authority as AIOCD-AWACS has not confirmed the company's claim", the company representative requested that whenever company's representation is not considered by NPPA, the same should be informed to the company with the reason of not considering the company's representation.
4. Company has already submitted copy of Price List in Form V of DPCO 2013 of Isosorbide-5-Mononitrate 10mg tablets and 20mg tablets along with review application.
5. For the comments given by NPPA in the brief of hearing about detail of trade margin based on AIOCD-AWACS data as on August, 2015, the company representative submitted that they are giving margin to retailers and wholesalers as per the existing standard trade practice prevalent in the pharmaceutical industry.

NPPA did not make any further submission.

**5. Examination:**

**i) Adenosine 3mg/ml Injection:-**

Company has pointed out that their two products of similar strength, viz. Adenoject 10ml Injection 1 and Adenoject 2ml Injection 1, have not been included in calculation sheet for calculating the ceiling price for Adenosine 3mg/ml Injection. NPPA stated that they considered the data provided by AIOCD-AWACS for the month of August, 2015. In support of their claim, the company attached Form V price list, showing that the abovesaid two formulations were marketed by the petitioner company. The PTR of Adenoject 10ml Injection 1 and Adenoject 2ml Injection 1 may be considered by NPPA, provided the market share of these products are more than 1% and subject to confirmation from Pharmatrac. In view of this, NPPA may be directed to consider the information/documentary proof submitted by the petitioner company about Adenoject 10ml Injection 1 and Adenoject 2ml Injection 1, and after getting confirmation from Pharmatrac, to refix the ceiling price of Adenosine 3mg/ml Injection, on merit, as per para 4 of DPCO, 2013.

**ii) Isosorbide -5- Mononitrate 10mg & 20mg tablet:-**

Company has stated that NPPA has considered Rs.16.50/tablet as PTR against the actual PTR as Rs.17.11 for Isosorbide -5-Mononitrate 10mg tablet and PTR of Rs.28.28/tablet against the actual PTR of Rs.29.30/tablet for Isosorbide -5-Mononitrate 20mg tablet. Company has also pointed out that they had submitted the representation on 02.11.2016 against the draft working sheet and also submitted additional details vide letter dated 22.11.2016 for the month of August, 2015. In reply, the NPPA stated that the representation and additional data was examined, but the same was not considered by the authority as AIOCD-AWACS has not confirmed the company's claim. In that case, NPPA should have shared the confirmation received from Pharmatrac (AIOCD-AWACS) with the petitioner company.

5.2 Keeping in view the above facts, NPPA may be directed to re-examine the information/documentary proof submitted by the petitioner company and after getting confirmation from Pharmatrac, to refix the ceiling prices of Isosorbide -5- Mononitrate 10mg & 20mg tablet, on merit.

**5. Government Decision:**

**“NPPA is hereby directed to consider the information/documentary proof submitted by the petitioner company about market share of Adenoject 10ml Injection 1 and Adenoject 2ml Injection 1, and after getting confirmation from Pharmatrac, to refix the ceiling price of Adenosine 3mg/ml Injection, on merit, as per para 4 of DPCO, 2013.”**

**“NPPA is further directed to re-examine the information/ documentary proof submitted by the petitioner company about actual PTRs of the company, and after verification, to refix the ceiling prices of Isosorbide -5- Mononitrate 10mg & 20mg tablet, on merit.”**

Issued on this date, the 24<sup>th</sup> day of August, 2017.

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

To

1. M/s. Sun Pharma Laboratories Limited,  
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Western Express Highway, Goregaon (E),  
Mumbai-400063.
2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building,  
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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