

**No. 31015/91/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Paviour Pharmaceuticals Pvt. Limited against price fixation of their formulation "Surfactant - suspension for intratracheal instillation" vide NPPA order No. S.O. 3722(E), dated 23.11.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 29.11.2017
2) NPPA notification under review S.O. No.3722(E), dated 23.11.2017
3) Record Note of discussions held in the personal hearing on 19.12.2017.**

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Paviour Pharmaceuticals Pvt. Limited (hereinafter called the petitioner) against notification S.O. No.3722(E), dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Surfactant - suspension for intratracheal instillation.

2. The petitioner has contended as under:

The Review petition is submitted as NPPA has erred in not considering company's objections which are made on following grounds:

(i) **Curosurf PTR & MAT DATA**

In spite of company's regular submission of PTR & MAT data to NPPA website, NPPA has not used company's data and used data from data collecting company, who have informed company that their data is not reliable. Further, in spite of company's submission of documentary proof of wrong data provided by data collecting company, NPPA has not considered company's actual data with proof.

(ii) **Custom duty**

The difference in custom duties among different surfactant as explained with supportive document has not been considered while fixing the ceiling price.

(iii) **Phospholipid content**

When their core group has recommended to use phospholipid content as unit for fixing the price, In spite of submissions of documentary evidence that different product have different purified phospholipid they have considered impurities as pure phospholipid which is against their own expert group recommendation.

(iv) **Expert Reports & WHO recommendation on surfactant**

In spite of company's submissions from various experts in India, who represent user doctors at national and state levels and WHO, who, have also defined surfactant, NPPA has used the definition of data collecting company, who are neither expert nor certified to define surfactant.

2. Thus, in view of above, company requested to:

- (i) keep this order in abeyance till the highlighted matter is discussed.
- (ii) request that based on current knowledge these products should not be considered as equal as 1:1.
- (iii) prices should be fixed based on current available market price separately for each product .

3. **Comments of NPPA:**

I. Ceiling price of **Surfactant- Suspension for Intratracheal Instillation** was notified as Rs. 60.69 per mg of Phospholipids in the pack vide S.O. 3722(E) dated 23.11.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Surfactant- Suspension for Intratracheal Instillation**. 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
	<p>Company has stated that NPPA has not considered their representation in reference to Office Memorandum dated 26.10.2017 against the draft version of proposed price calculation sheet.</p> <p>Company has also pointed out here that NPPA has erred in not considering their points mentioned below:-</p> <p>1. Curosurf PTR & MAT DATA In spite of their regular submission of PTR & MAT DATA to NPPA website, NPPA had not used their data and used data from data collecting company, who have informed them that their data is not reliable. Further, in spite of their submission of documentary proof of wrong data provided by data collecting company NPPA have not considered their actual data.</p>	<p>NPPA fixed ceiling price of Surfactant- Suspension for Intratracheal Instillation as Rs.60.69 per mg of Phospholipids in the pack vide S.O. 3722(E) dated 23.11.2017 considering the data submitted by pharma-trac for the period of August 2015.</p> <p>Based on the representation and data submitted by the company on the draft working sheet, the formulation was placed before the committee of experts under Para 11(3&4) of DPCO 2013. Based on the recommendation of committee of expert the ceiling price of Surfactant- Suspension for Intratracheal Instillation was fixed.</p>

	<p>2. Custom Duty The difference in custom duties among different surfactant NPPA has not considered the same while fixing the ceiling price.</p> <p>3. Phospholipid content NPPA has not considered Phospholipid content as unit for fixing the ceiling price although expert committee recommended the same. Company has also stated that they have submitted the document in support of their claim even then NPPA has considered impurities as pure phospholipid which is contrary to the recommendation of expert committee.</p> <p>4. Expert Reports & WHO recommendation on surfactant In spite of company submissions from various expert in India, who represent user doctors at National and State levels and WHO, who, have also defined surfactant, NPPA has used the definition of data collecting company, who are neither expert nor certified to define surfactant.</p> <p>Company requested that price should be fixed based on current available market price separately for each product.</p>	<p>There is no provision in DPCO 2013 to consider the duties while fixing the ceiling price.</p> <p>NLEM 2015 of DPCO 2013 does not differentiate to fix ceiling price based on Phospholipid content.</p> <p>Company request is not as per the provisions of DPCO 2013.</p>
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III. Company has not challenged S.O. No. 3722(E) dated 23.11.2017 in High Court.

4. During the personal hearing, the representative of the Company submitted the following points to prove that clubbing of dissimilars by NPPA was illogical, unreasonable and against all settled principles of medical ethics patent documents and even the views earlier taken by Central Government in the Ministry of Finance, tender documents of various State Governments and is, therefore, against principles of natural justice:-

a. Curosurf is a biological and non-pharmacopoeial product

(i) Paviour highlighted that the report of Core-Committee of NLEM 2015 has recommended that :-

“Biologicals to be considered differently based on different source, process, technology and composition”

Curosurf (Poractant alfa) being a biological product has been clubbed with Surfact of Sun Pharma, which is synthetic surfactant. Other surfactants are also biologically different.

(ii) Paviour also referred to Para 11(3) of DPCO 2013 which states that :-

“Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale.....”

Since Curosurf has 99% phospholipids and surfactant protein B which is important constituent helping in Phospholipids to spread in lungs which are required to be delivered by a Specialist neonatologist directly into the lungs of new born for post natal lung function. Curosurf reduces neonatal mortality significantly as compared to other surfactants.. Separate price under para 11(3) is, therefore justified for Curosurf (Poractant Alfa) on grounds of therapeutic rationale.

(iii) DPCO 2013 Para 11(4): Inter-alia mentions setting up of expert group.

Though the product was stated to be considered by an expert committee of NPPA, Paviour mentioned that Curosurf is a specialized hospital product and, therefore, association of a super-specialist Neonatologist in the expert committee is a must without which it is not possible to deliver justice to the families of those new borns who are born with **neonatal deficiency**.

b. Government document to prove clubbing of dissimilar :-

- (i) **Custom Tariff** issued by Ministry of Finance, Government of India has differentiated Curosurf (Poractant Alfa) from other surfactants by putting them in 2 different chapters, hence having different custom duties. Otherwise, one product cannot be put in two different entries/ chapters of custom tariff.
- (ii) **Government Tenders:-** Paviour further pointed out that in various tenders issued by various State Governments quotations have been called for Curosurf separately from other surfactants in the same tender. There cannot be two different items in one NIT (Notice Inviting Tender) for one product. This shows tender inviting Governments recognize difference in Curosurf and other surfactants.

c. Different generic names of differential biological surfactants

Different natural surfactants have differential generic names (Ref.: Table 2 of publication “*Fox, G.F., Sothinathan, U (2005). The choice of surfactant for treatment of respiratory distress syndrome in preterm infants: A review of the evidence. Infant 1(1): 8-12*”)

d. Expert Opinion on dissimilars

Paviour brought to the kind attention of Reviewing Authority various documents to justify that different surfactants could not be clubbed as same product. These documents are :-

- (i) National President, Indian Academy of Paediatrics 2017
- (ii) Associate Professor, Govt. Hospital for Women & Children, Madras Medical College, Egmore, Chennai
- (iii) Secretary General, National Neonatology Forum
- (iv) President, Chhattisgarh Academy of Pediatrics
- (v) Patent data for different surfactants
- (vi) Letter from manufacturer

1. DATA RELATED ISSUES

- (i) **Pharma Trac letter:-** Data of Paviour has not been correctly taken by Pharma Trac. A copy of e-mail from PharmaTrac states as under:-

“Curosurf seems to be predominantly sold in hospital, we might not be appropriately capturing the same”

- (ii) **Government Orders:-** Paviour have submitted government order copies (Institutional price) for the prevailing price of 2015
- (iii) **Precedence of considering Institutional Price by NPPA:-**Attention was drawn towards S.O. 3725(E) dt 23rd Nov, 2015 of NPPA vide which NPPA has fixed the ceiling price of Coagulation Factor IX by Baxalta fixed on basis of Institutional Price. where ceiling price was fixed on the basis of Institutional Price.
- (iv) **Alternate Source when Pharma Trac does not capture appropriate data:-** Source of market data, as per Para 9 of DPCO 2013, is market data specializing company i.e. IMS-Health which has been substituted by NPPA with PharmaTrac.

If PharmaTrac is not appropriately capturing Curosurf data, government under Para 9(2) of DPCO 2013 is empowered to depend on other appropriate mechanism of collecting or obtaining market based data. NPPA has already launched IPDMS and Curosurf data has already been uploaded on IPDMS, NPPA could resort to the available data on IPDMS.

2. CURRENT IMPORT PRICE / JUSTIFICATION OF PRICE / AVAILABILITY CRISIS

Paviour has highlighted that Import price of Curosurf in India is Curosurf 1.5 ml – Rs. 7633.85, Curosurf 3 ml – Rs. 12,723.08 while landing cost is 2 to 3 % more which consists of bank charges, shipment clearing charges and transportation to warehouse, however these import prices and landing cost of Curosurf are significantly lower than the prices in other similar countries and no indigenously

manufactured product are available, so unjustifiable price to manufacturer may lead to shortages of the product which defeats the primary aim of NPPA :-

“to ensure adequate availability of essential and lifesaving drugs at affordable prices and in doing so, it carefully balances the interests of both the producers and the consumers”

Thereby, it is requested:-

- (1) To keep NPPA order S.O. 3722(E) for Item no. 6 (Surfactant – Suspension of intratracheal instillation) which includes Curosurf, in abeyance till Department of Pharmaceuticals settles the Review Petition.
- (2) Curosurf to be treated differently as it is a different surfactant.
- (3) While calculating ceiling price of Curosurf, Institutional price / procurement price of Curosurf to be considered (referring to Order S.O. 3725(E) dt 23rd Nov, 2017 for Coagulation factor IX).

In addition to the comments furnished above, NPPA representative further submitted that the ceiling price of surfactant – suspension for intratracheal instillation was fixed based on the recommendation of the Committee of Experts under para 11(3&4) of DPCO, 2013.

5. Examination:

Company, in its review application, stated that their product Curosurf is a biological and non-pharmacopoeial product and should not be clubbed with other surfactants, which are biologically different. The company's representatives, during the personal hearing, submitted that Curosurf has 99% phospholipids and surfactant protein B which is important constituent helping in Phospholipids to spread in lungs which are required to be delivered by a Specialist Neonatologist directly into the lungs of new born for post natal lung function. Curosurf reduces neonatal mortality significantly as compared to other surfactants. Separate price under para 11(3) is, therefore justified for Curosurf (Poractant Alfa) on grounds of therapeutic rationale. Company also stated that though the product was stated to be considered by an expert committee of NPPA, but since Curosurf is a specialized hospital product, association of a super-specialist Neonatologist in the expert committee is a must, without which it is not possible to deliver justice to the families of those new borns who are born with neonatal deficiency.

NPPA has fixed the ceiling price based on the recommendation of Expert Committee under para 11(3&4) of DPCO, 2013. The Expert Committee is well represented by very senior Professors and Doctors of AIIMS and other experts in the field, who are capable enough to understand the therapeutic rationale of the any drug/formulation. In medical field, there are numerous segments and every segment has got super-specialist. It is not possible to induct super-specialist in the Expert

Committee for any particular drug/formulation. Therefore, the request of the company to induct Neonatologist in the Expert Committee cannot be accepted.

The company in its submission also contended that the PTR and MAT data used by NPPA is not reliable. The company stated that the data of supplies made to hospitals of their brand Curosurf is not considered while calculating the ceiling price of the subject formulation. The data of Government supplies / institutional sale is being considered when there is no retail sale data is available and the product is sold exclusively to Government hospitals/institutions. As can be seen from the calculation sheet, the company's retail sale data of Curosurf brand is available. Therefore, the data used by NPPA is in order.

Company also requested to consider difference in custom duties among different surfactant while fixing the ceiling price. As there is no provision in DPCO, 2013 to consider the duties while fixing the ceiling price, the request of the company cannot be accepted.

Government Decision:

“NPPA has fixed the ceiling price based on the recommendation of Expert Committee under para 11(3&4) of DPCO, 2013. Therefore, the request of the company to refer the matter again to Expert Committee by inducting Neonatologist in the Committee cannot be accepted.”

“The data of Government supplies / institutional sale is being considered when there is no retail sale data is available and the product is sold exclusively to Government hospitals/institutions. The retail sale data of the subject formulation is available. Therefore, the data used by NPPA is in order.”

“There is no provision in DPCO, 2013 to consider the duties while fixing the ceiling price. Therefore, the request of the company to consider difference in custom duties among different surfactant while fixing the ceiling price cannot be accepted.”

Issued on this date of 16th day of January, 2018.

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

To

- 1. M/s. Paviour Pharmaceuticals Pvt. Limited,
311-312, Suneja Tower – 1,
District Centre, Janak Puri,
New Delhi-110058.**

**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**