

**No. 31015/94/2017-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 Abbott India Limited against price fixation of their formulation "Surfactants" 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 08.12.2017
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 16.01.2018.**

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott India 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 Surfactants.

2. The petitioner has contended as under:

1. NPPA vide O.M. No. 8(34)/2016/DP/NPPA/Div.II dated May 08, 2017 put up the draft working calculation sheets for proposed ceiling prices/retail prices of Surfactants at Rs 2152.86 per ml.

2. NPPA vide O.M No. 8(35)/2016/DP/NPPA/Div-II dated October 26, 2017 put up a revised draft calculation sheet for proposed ceiling prices/retail prices fixation of Surfactants using a new pricing methodology and proposed to fix ceiling price at Rs. 60.69 per mg.

3. Company filed representation against the draft working sheet on November 9, 2017 challenging both the proposed new pricing methodology which is not provided for in DPCO, 2013 and the calculation errors in the draft calculation sheet put up by the NPPA. Company also provided documentary evidence for the calculation errors.

4. On November 20, 2017, company filed another representation to reiterate the specific provisions of DPCO 2013 which would be violated by the proposed new pricing methodology of NPPA.

5. NPPA in its authority meeting on November 22, 2017 wilfully ignored the apparent contravention of DPCO provisions and errors in calculation of ceiling price pointed out by the company, supported by documentary evidences, vide its representations submitted on November 9, 2017 and November 20, 2017 and went ahead to notify the incorrect price of Surfactants on November 23, 2017 in complete

disregard of the provisions of DPCO 2013 and in abrogation of powers delegated to NPPA by the Government of India in respect of DPCO 2013.

6. Company submitted that the ceiling price notified by NPPA vide Notification S.O. No. 3722 (E) dated November 23, 2017 for Surfactants -an injectable -on the basis of per unit weight is outrightly in contravention of Para 11(1) of the DPCO 2013.

Para 11(1) of the DPCO 2013 very clearly mandates that for Injectables the price has to be fixed on the basis of **per unit volume**, which in the case of Injectables, would be on **per 'ml' basis**.

As per past practices of price fixation of injections, all such price fixations are done on a per unit volume basis. The decision of the NPPA to deviate from both the mandate of law as well as the established practise of NPPA itself is arbitrary and thus, not sustainable in the eyes of law.

7. Company further submitted that under the scheme of distribution of powers between the legislature, the executive and the allied agencies of the executive, in the eyes of law, NPPA is a delegated authority under the Government of India (Department of Pharmaceuticals). As per the established principles of administrative law, a delegated authority does not have the power to legislate. Hence, as a regulatory authority functioning under powers of DPCO 2013, that have been delegated by the Government of India (Department of Pharmaceuticals), NPPA is authorised only to execute and enforce the mandate of DPCO 2013. The very act of using a different parameter in a one-off case and the set parameters not being a part of DPCO 2013 is tantamount to de-facto amendment of DPCO 2013, which is in legal terms a legislative activity for which NPPA does not have the legislative power.

Hon'ble Supreme Court held in the case of *India Cynamide vs Union of India* 1987 AIR 1802 promulgating Drug Price Control Order is a legislative activity. Hence, NPPA being a delegated authority of the executive does not have the power to de facto amend a legislation. On this very count, the actions of NPPA resulting in the price fixation of Surfactants on the basis of per unit weight of a constituent therein, should be vitiated and struck down.

8. The principle that NPPA does not have the powers to arrive at its own formulae or methodology for price fixation and it needs to mandatorily apply the provisions of DPCO 2013 has been recently upheld by the DOP review order dated September 18, 2017 in the case of review application filed by M/s Cadila Healthcare Limited.

9. NPPA has published the work sheet it had used to fix the ceiling price without prejudice to the above averments, there are also two errors in calculation which are as under:

(i) Surfactants- suspension for intratracheal instillation is classified under excise exempt category and the GST factor 0.95905 should not be applied for fixing price of this formulation.

(ii) NPPA has considered the price of M/s. Sun Pharma Laboratories Ltd.'s brand Surfact 108mg Injection 10ml for calculating the Ceiling price of Surfactants. This brand seems to have been discontinued.

(iii) Company also furnished IMS data establishing that Surfact 108mg Injection 10ml of M/s. Sun Pharma Laboratories Ltd., seems to have been discontinued since 2015 onwards.

10. In light of the above facts, company requested the DOP to:

a. Direct NPPA to revise the ceiling price of Surfactants on the basis of per ml using the methodology applied in the draft calculation sheet of May 8, 2017;

b. Direct the NPPA that while revising the ceiling price of Surfactants the GST factor of 0.95905 should not be applied. Further, NPPA should not consider M/s Sun Pharma Laboratories Ltd.'s brand Surfact 108mg Injection 10ml for calculating the ceiling price of Surfactants.

3. **Comments of NPPA:**

I. Ceiling price of Surfactants was notified as Rs. 60.69 per mg of phospholipids per pack vide S.O. 3722 (E) dated 23.11.2017 as per para 4,6,10,11,14,16,17, and 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of Surfactants. 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 to 5)	Company stated that NPPA vide O.M. No.8(34)/2016/DP/NPPA/Div.II dated May 08, 2017 put up the draft working calculation sheet for proposed ceiling prices/ retail prices of Surfactants at Rs. 2152.86 per ml. NPPA vide O.M. No.8(35)/2016/DP/NPPA/Div.II dated Oct 26, 2017 put up a revise draft calculation sheet for proposed ceiling prices/retail prices fixation of Surfactants using a new pricing methodology and proposed to fix ceiling price at Rs. 60.69 pr mg. Company filed representation against the draft working sheet on Nov 09, 2017 challenging both the proposed new pricing methodology which not provided for in DPCO, 2013. On Nov 20, 2017 Company filed another representation to reiterate the specific provisions of DPCO, 2013 which would be violated by the	NPPA fixed ceiling price of Surfactants suspension as Rs. 60.69 per mg of phospholipids in the pack vide so 3722 (E) dated 23.11.2017 considering the data submitted by Pharma trac for the period of August, 2015. Based on the representation and data submitted by the companies viz. M/s Paviour Pharmaceuticals Pvt. Ltd., Sun Pharmaceuticals and Abbott India Ltd. the formulation was discussed in 5 th meeting of committee of experts held on 21.07.2017. C.O.E. directed to collect information from manufacturers. Accordingly letters were written to M/s Cipla Ltd., M/s Sun Pharma

	<p>proposed new pricing of methodology of NPPA. Company also requested for a personal hearing in both their representation but same were denied by NPPA.</p>	<p>Laboratories Ltd. and M/s Paviour Pharma Ltd. The case was again discussed in 6th meeting of committee of experts held on 13.10.2017. The committee recommended that price may be considered for fixation based on major component i.e. Phospholipidis and in milligram (mg) as units.</p>
(6 to 8)	<p>Company is of the opinion that NPPA in its authority meeting on Nov 22, 2017 willfully ignored the apparent contravention of DPCO provisions and errors in calculation of ceiling price pointed out by the Company, supported by documentary evidences, vide its representations submitted on Nov 09 and Nov 20, 2017 and went ahead to notify the incorrect price of Surfactants on Nov 23, 2017. Fixing the ceiling price of Surfactants – injectable –on the incorrect basis of per unit weight, is contravention para 11 (1) of the DPCO, 2013 .</p>	<p>NPPA considered the recommendations of committee of experts constituted under para 11 (3&4) of DPCO, 2013. Since, the para 11 (3) of DPCO, 2013 is involved which is overriding the para 11(1), para 11 (3) state – Notwithstanding anything contained in sub-paragraph (1) and (2), in the case injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule -1 of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pace size or dosage compliance or content in the pack namely liquid, gaseous or any other form in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23of 1940) and the rules made thereunder for the formulation.</p>
(9 to 10)	<p>Company has also stated that under the scheme of distribution of powers between the legislature, the executive and allied agencies of the executive, in the eyes of law, NPPA is a delegated</p>	<p>NPPA has cited upon para 11 (3) of DPCO, 2013 and executed all act and order as per DPCO, 2013.</p>

(11)	<p>authority under the Govt. of India (Department of Pharmaceuticals). As per the established principles of administrative law, a delegated authority does not have the power to legislate. Hence, as a regulatory authority functioning under the power DPCO, 2013, that have been delegated by Govt. of India, (Department of Pharmaceuticals), NPPA is authorized only to execute and enforce the mandate of DPCO, 2013. The very act of using different parameters in a one- of case and the set parameters not being a part of DPCO, 2013 is tantamount to De-facto amendment of DPCO, 2013, which is in legal terms a legislative activity for which NPPA does not have the legislative power. In support of their statement company mentioned Supreme Court decision in the case of India Cynamide vs Union of India 1987 AIR 1802 and DoP review order dated Sep 18, 2017 in the case of review application filed by M/s Cadila Healthcare Ltd.</p> <p>Company also pointed out two errors in the calculation :</p> <p>i) Surfactants – Suspension for intratracheal instillation is classified under excise exempt category and the GST factor 0.95905 should not be applied for fixing price of this formulation.</p> <p>ii) NPPA has considered the price of M/s Sun Pharma Laboratories Ltd.'s brand Surfact 108 mg injection 10 ml for calculating the ceiling price of Surfactants. This brand seems to have been discontinued. We have also pointed this out to Pharmatrac- AWACS and they are also in the process of verifying this.</p> <p>iii) We are also enclosing IMS data which clearly establishes that Surfact 108 mg Injection 10 ml of M/s Sun Pharma</p>	<p>Issues raised by company have no merit and have no relevance with provision of DPCO, 2013.</p> <p>(i) NPPA has applied multiplication factor of 0.95905 after consideration of notification no. 6/2016-customs dated 28.01.2016. Thus, the contention of the company is not tenable.</p> <p>The company do not give any specific entry for excise exemption as 30.06.2017.</p> <p>(ii) Letters were written to M/s Sun Labs and they have not confirmed about discontinuation. Moreover, the data to IMS submitted by Abbott also shows the sales.</p> <p>Company has not submitted any documentary proof in support of the discontinuation of the Surfact 108 mg Injection 10 ml. Letter was also written to M/s Sun Pharma Laboratories Ltd. and they have not informed that they have discontinued their brand Surfact 108 mg Injection 10 ml. In absence of documentary proof company's request to exclude Surfact 108 mg Injection 10 ml from</p>
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(12)	<p>Laboratories Ltd., seems 2015 onward.</p> <p>Company stated that they have 100% IPDMS complaint and are regularly filing the statutory forms in IPDMS time to time and constantly updating the same. We have also not challenged this notification in any court. Company also requested to revised the ceiling price of Surfactants on the basis of per ml using the methodology applied in draft calculation sheet of May 18, 2017 as well as not to consider M/s Sun Pharma Laboratories Ltd.'s brand Surfact 108 mg Injection 10 ml for calculating the ceiling price of Surfactants.</p>	<p>calculation sheet could not be considered.</p>
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4. During the personal hearing the representatives of the company submitted that –
 - i. As per Para 11 (1) of the DPCO 2013, which clearly mandates that for injectables the price has to be fixed on the basis of **per unit volume**, which in the case of injectables, would be on **per 'ml' basis**. Hence, NPPA should fix the CP as per the original draft work sheet published by NPPA vide O.M. No. 8(34)/2016/DP/NPPA/Div.II dated May 08, 2017 at Rs 2,152.86 per ml.
 - ii. Further, under the scheme of distribution of powers between the legislature, the executive and allied agencies of the executive, in the eyes of law, NPPA is a delegated authority under the Govt. of India (Department of Pharmaceuticals). As per the established principles of administrative law, a delegated authority does not have the power to legislate. Hence, as a regulatory authority functioning under the power DPCO, 2013, that have been delegated by Govt. of India, (Department of Pharmaceuticals), NPPA is authorized only to execute and enforce the mandate of DPCO, 2013. The very act of using different parameters in a one- of case and the set parameters not being a part of DPCO, 2013 is tantamount to De-facto amendment of DPCO, 2013, which is in legal terms a legislative activity for which NPPA does not have the legislative power. In support of their statement, company representatives mentioned the Supreme Court decision in the case of India Cynamide vs Union of India 1987 AIR 1802 and DoP review order dated Sep 18, 2017 in the case of review application filed by M/s Cadila Healthcare Ltd.
 - iii. Further, without prejudice to the above, under the 'per mg' pricing methodology adopted by NPPA to fix CP based on the content of phospholipids, company representatives pointed out that NPPA can only fix CP for each strength separately, as enshrined in Para 11(3) of the DPCO, 2013.
 - iv. As per Para 11 (3), NPPA can only fix separate ceiling prices based on different strengths, delivery routes, technical advancements etc and not ceiling price of the entire category.

- v. NPPA has not provided any confirmation of existence of Sun Pharma's brand even after company representatives provided evidence of discontinuation of the product via IMS data which reflects 0.1 (2015), 0.1 (2016) and 0.0 (2017) unit volumes sales. Company representatives requested the Reviewing Authority to direct NPPA to conclusively provide the factual position.
- vi. Company representatives also pointed that Survanta is a Beractant and that the NPPA has incorrectly applied multiplication factor of 0.95905 to fix the CP instead of a factor of 1.0. The product is currently Excise Free and is covered under the Notification No. 6/2016-customs dated 28.01.2016. Company representatives provided documentary evidence in the form of medical journal <https://www.omicsonline.org/is-there-a-difference-in-surfactant-treatment-of-respiratory-distress-syndrome-in-premature-neonates-2161-105X.S13-004.pdf> to clarify NPPA's contention that the NLEM 2015 states Surfactants as 'Suspension for intratracheal instillation' whereas the Excise exemption notifications nomenclature is "Beractant intra tracheal suspension."
- vii. The relevant section from the journal is as below:

"These sentinel reports lead to our current strategies for the surfactant treatment of RDS in premature infants that began in 1989, with the Food and Drug Administration (FDA) approval of the synthetic surfactant colfosceril palmitate suspension (Exosurf®), closely followed by approval of beractant (Survanta®), the first animal derived surfactant." The Company representatives also requested the same may be verified through medical experts by the Reviewing Authority.
- viii. Once validated by medical experts that Survanta is a Beractant; and if other Surfactants do not qualify as Beractants, then in such circumstances the company representatives pointed out that by virtue of being the only Beractant in the category of Surfactants, it therefore qualifies for a separate CP as provided under Para 11 (3) of the DPCO 2013.

4.2 In reply, the NPPA representative stated that the ceiling price of surfactants was notified based on the recommendation by the Committee of Experts under para 11(3&4) of DPCO, 2013. Further, excise factor of 0.95905 was taken while fixing the ceiling price of Surfactants since no excise exemption notification can be seen in the custom order in respect of surfactants.

5. **Examination:**

In the review application, the company mainly raised the following three issues :-

- (i) Fixing the ceiling price of Surfactants – injectable –on the incorrect basis of per unit weight, i.e. on "per mg" instead of "per ml" basis is contravention of para 11(1) of the DPCO, 2013.
- (ii) Surfactants – Suspension for intratracheal instillation is classified under excise exempt category and the GST factor 0.95905 should not be applied for fixing price of this formulation.
- (iii) NPPA has considered the price of M/s Sun Pharma Laboratories Ltd.'s brand Surfact 108 mg injection 10 ml for calculating the ceiling price of Surfactants. This brand seems to have been discontinued.

5.2(i) As regards issue (i) raised above, NPPA has fixed the ceiling price of Surfactants based on the recommendation of Committee of Experts held on 13.10.2017. The Committee of Experts observed that different surfactants available in the market have highly variable contents of Phospholipids per ml., which varies from 10.8 mg/ml to 80 mg/ml and the dosage varies from 1.25ml/kg to 7ml/kg. The Committee also observed that there are other components in the surfactants but are of less consequence. Therefore, the Committee recommended that the price may be considered for fixation based on major component, i.e. Phospholipids and in milligram(mg) as units.

As per provision in para 11(1) the price has to be fixed on the dosage basis, which according to company, in case of injectables, would be on per ml basis. However, para 11(3) provides that “notwithstanding anything contained in sub-paragraph (1) and (2), in the case of **injections** or inhalation or any other medicine **for which dosage form or strength or both are not specified in Schedule-I** of DPCO, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size of **dosage compliance** or content in the pack namely liquid, gaseous or any other form, in the **unit dosage** as the case may be.....”. The subject formulation Surfactant is listed as Section 24.3 of Schedule-I of DPCO, 2013 wherein dosage form is not mentioned. The above recommendation of Committee of Experts is based on provision 11(3&4) of DPCO, 2013, which overrides the para 11(1) of DPCO. Therefore, the contention of the company that fixing the ceiling price of Surfactants on the incorrect basis of per unit weight, i.e. on “per mg” instead of “per ml” basis is in contravention of para 11(1) of the DPCO, 2013 has got no merit. In view of this, the request to revise the ceiling price of Surfactants on the basis of per ml basis cannot be agreed to.

5.2(ii) The other issue raised by the company is against application of GST factor 0.95905 on the ground that Surfactants – Suspension for intratracheal instillation is classified under excise exempt category. In this connection, NPPA stated that the multiplication factor of 0.95905 is applied after consideration of notification no.6/2016-customs, dated 20.01.2016, vide which Department of Revenue, Ministry of Finance has removed the exemption of subject formulation.

The contention of the petitioner company that Surfants is classified under excise exemption category, has got no relevance as levy of or exemption from any duties (excise/custom) has no bearing on fixation or revision of ceiling prices under the provisions of DPCO, 2013. The ceiling prices are fixed on market based data and not on cost based data. As such any plea for revision/refixation of ceiling prices on account of any modification in the applicable duty rates is not tenable under the provisions of DPCO, 2013. Applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Therefore, the request of the company cannot be considered.

5.2(iii) The company also raised the issue (iii), wherein it stated that NPPA has considered the price of M/s Sun Pharma Laboratories Ltd.’s discontinued brand Surfact 108 mg injection 10 ml for calculating the ceiling price of Surfactants. In support of its claim, the company furnished the IMS data. However, while fixing the prices of any formulation, the Pharmatrac data is being considered by NPPA. Moreover, NPPA in its reply stated that M/s Sun Pharma Laboratories did not inform that their brand Surfact 108mg injection 10 ml. has been discontinued. Company also has not submitted any

documentary proof in support of the discontinuation of Surfact 108mg injection 10ml. In view this, the grievance raised by the company cannot be considered.

5.3 In view of the above, all the three grievances raised by the company in its review application cannot be considered and the application may be rejected.

6. **Government Decision:**

“The ceiling price of Surfactants on ‘per mg basis’ was fixed on the recommendation of Committee of Experts under para 11(3&4) of DPCO, 2013, which overrides the para 11(1) of DPCO. The contention of the company that fixing the ceiling price of Surfactants on “per mg” instead of “per ml” basis is in contravention of para 11(1) of the DPCO, 2013 has got no merit and cannot be agreed to.”

“Levy of or exemption from any duties (excise/custom) has no bearing on fixation or revision of ceiling prices under the provisions of DPCO, 2013. Any plea for revision/refixation of ceiling prices on account of any modification in the applicable duty rates is not tenable under the provisions of DPCO, 2013. Applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Hence, the request of the company cannot be considered.”

“In the absence of any documentary proof in support of the discontinuation of Surfact 108mg injection 10ml., being manufactured by M/s Sun Pharma Laboratories Ltd., the grievance raised by the company cannot be considered.”

“All the three grievances raised by the company in its review application cannot be considered and the application stands rejected.”

Issued on this date of 21st day of March, 2018.

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

To

1. M/s. Abbott India Limited,
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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