

**No. 31015/60/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Alembic Pharmaceuticals Limited against price fixation of “Erythromycin Estolate Tablets 250mg; Erythromycin Tablets 500mg and Erythromycin Estolate Syrup 125mg./5ml” vide NPPA order No. S.O. 1526(E), dated 11.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 31.05.2017
2) NPPA notification under review S.O. 1526(E), dated 11.05.2017
3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Alembic Pharmaceuticals Limited (hereinafter called the petitioner) against notification S.O. No.1526(E), dated 11.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Erythromycin Estolate Tablets 250mg; Erythromycin Tablets 500mg and Erythromycin Estolate Syrup 125mg./5ml.

2. The petitioner has contended as under:-

- I. Erythromycin formulations namely Erythromycin Tablet 500mg, Erythromycin Tablet 250mg and Erythromycin Syrup 125mg/5ml have been shifted to Non-scheduled category vide Government Notification No. S.O. 701(E) dated 10.03.2016. In this connection the Department of Pharmaceuticals has also issued an OM bearing No. F. No. 31026/31/2016-PI.I dated 20.04.2017, wherein NPPA has been directed to regulate the Scheduled drugs shifted to Non-scheduled category as NON-SCHEDULED drugs under para 20 of DPCO, 2013.
- II. NPPA has fixed vide its S.O. No. 1526 (E) dated 11.05.2017 the ceiling prices of above said Non-scheduled formulations referring to the paras 4,10,11,14,16,17 and 18 of DPCO, 2013, which is inconsistent with provisions of DPCO, 2013.
- III. While issuing the impugned notification stated above, NPPA has also failed to appreciate its own OM No. F. No. 19 (119)/2014/Div-II/NPPA dated 01.05.2017 issued in respect of such Scheduled formulations shifted Non-scheduled category.
- IV. They represented to NPPA to withdraw the same as it was contrary to provisions of DPCO, 2013 vide our letter dated 12.05.2017. They also submitted that on the day the notification was uploaded i.e. 12-05-2017 the S.O. No. was blank.

However, the downloaded file name contained the number 2704 which was wrongly presumed by them as S.O. No. Hence, the S.O. appearing in their Representation to NPPA and DOP was erroneously mentioned as 2704 instead of 1526 as later updated on NPPA website.

- V. They have also requested the Department of Pharmaceuticals to direct NPPA to withdraw the said notification, from the date of notification vide their letter dated 22.05.2017.
- VI. In view of the above facts, submissions and provisions of DPCO, 2013, company submitted that the above said price notification of NPPA, is without any rationale or legal basis clearly arbitrary, unreasonable and hence may not be implemented in so far as the prices notified as ceiling prices in respect of Erythromycin Tablet 500mg, Erythromycin Tablet 250mg and Erythromycin Syrup 125mg/5ml.
- VII. They submitted that they are lawfully abiding by Para 20 of the DPCO, 2013 which monitors prices of non-scheduled formulations as provided in the DOP' OM No. 31026/31/2016-PI.I dated 20.04.2017.
- VIII. In view of NPPA arbitrarily fixing the prices of non-scheduled formulations in complete deviance from the very object and purpose of DPCO, 2013, company highlighted the following:
 - (i) There is no corresponding provision in DPCO, 2013.
 - (ii) Pursuant to notification dated March 10, 2016, under S.O. No. 701(E) we are entitled to increase the price to the extent of not being more than ten per cent of maximum retail price during preceding twelve month.
 - (iii) Para 4,10,11,14,16,17 and 18 of the DPCO 2013 under which S.O. No. 1526(E) dated 11-05-2017 is issued applies to scheduled formulations only.

Company requested this Department to direct NPPA to withdraw impugned notification S.O. 1526(E) dated 11.05.2017 from the date of notification itself.

3. **Comments of NPPA:**

- I. M/s Alembic Pharmaceutical Limited has submitted their representation vide letter NIL dated 12.5.2017 and 22.5.2017 for withdraw of above said price notification. Company has raised the following points:-

S. No.	Company's Grievances	NPPA's comments
1.	NPPA has fixed vide S.O. 1526(E) dated 11.5.2017 the ceiling prices of above said non-scheduled formulations referring paras 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 which is in consistent with provisions of	Attention is drawn to the review order passed by reviewing Authority i.e. DoP vide review order no 31015/20/2015-PI.I dated 30.8.2016 (copy enclosed), wherein direction and Government decision inter-alia

	<p>DPCO, 2013.</p> <p>While issuing the impugned notification stated above, NPPA has also failed to appreciate its own OM No. F. No. 19(119)/2014/Div.II/NPPA dated 01.5.2017 issued in respect of such scheduled formulation sifted non-scheduled category.</p> <p>After issuing of NPPA's said notification, we represented to NPPA to withdraw the same as it was contrary to provisions of DPCO, 2013 vide our letter dated 12.5.2017.</p> <p>Erythromycin formulations namely Erythromycin Estolate Tablets 500mg, Erythromycin Estolate Tablets 250mg and Erythromycin Estolate Syrup 125mg/5ml have been shifted to non-scheduled category vide S.O. 701(E) dated 10.3.2016. in this connection DoP has also issued an OM bearing F. No. 31026/31/2016-PI.I dated 27.4.2017, wherein NPPA has been directed to regulate the schedule drugs sifted to non-scheduled category as non-scheduled drugs under para 20 of DPCO, 2013.</p>	<p>have been given as under "in respect of Erythromycin Estolate Syrup and Erythromycin Estolate Tablets and Chloroquine Phosphate Injection, NPPA may allow WPI on 20.12.2014 i.e. after one year from the date of fixation of prices under DPCO 1995 and the same data after using the WPI will be considered by NPPA for price fixation with effect from 01.04.2015. Any increase taken by the company between 20.12.2013 and 20.12.2014 is not as per the DPCO provisions and, therefore, overcharging amount may be recovered from the company".</p> <p>Accordingly, in line with direction in aforesaid review order, read with OM 31026/31/2016-PI.I (Pt.-III) dated 20.4.2017 issued by the DoP, the above said S.O. 1526(E) dated 11.5.2017 has been issued by the NPPA in compliance thereof after consultation with Department of Pharmaceuticals. Moreover, the issue of overpricing and recovering are not covered under the provisions of para 31 and the aggrieved companies in such cases can only seek legal remedy in such cases.</p>
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4. During the personal hearing, the representative of the Company reiterated that the formulations under discussion namely Erythromycin Estolate Tablets 250mg, 500mg and Erythromycin Syrup 125/5ml, are non scheduled formulations in accordance with the notification SO 701 (E) dated 10th March 2016 and Office Memorandum issued by the Department of Pharmaceutical on 20th April, 2017 clarifying that the formulations shifted in the non scheduled category w.e.f. 10th March, 2016 are to be regulated as non scheduled formulations in terms of para 20 of DPCO, 2013. The Company representative also confirmed that they are accordingly complying with the provision of para 20 of DPCO, 2013. In view of this, NPPA should not have notified the ceiling prices of Erythromycin Estolate Tablets 250mg, 500mg and Erythromycin Syrup 125/5ml vide SO 1526 (E) dated 11th May, 2017, categorizing these formulations as scheduled formulations, subsequent to the notification of the Department 701 (E) dated 10th March, 2016 and OM dated 20th April, 2017. In this matter, the representative of the Company also pointed out that the NPPA itself vide their Office Memorandum 19(119)/2014/Div II/NPPA dated 1st May, 2017 had withdrawn earlier OM, dated 6th April, 2016, issued by them in regard to formulations shifted to non scheduled categories due to amendment of Schedule 1 of DPCO, 2013. The representative of the

Company requested the Reviewing Authority to direct NPPA to withdraw the impugned Notification SO 1526 (E) dated 11th May, 2017 retrospectively and accordingly categorize the formulations under reference as non scheduled formulations from the date of the said notification itself.

NPPA representative, in addition to the reply stated above, further stated that the notification was issued to comply with the review order no. 31015/20/2015-PI.I, dated 30.8.2016.

5. Examination:

The ceiling prices of the formulations **Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg, Erythromycin Syrup 125mg.5ml. and Chloroquine Phosphate Injection 40mg/ml** were fixed by NPPA vide SO 1526(E), dated 11.05.2017 to comply with the Review Order No.31015/20/2015-PI.I, issued by DoP on 30th August, 2016. The Review order was issued on the review petitions filed by M/s IPCA Laboratories Ltd. in April, 2015 against SO No.834(E), dated 25.3.2015. At that time, the subject formulations were scheduled medicines in NLEM 2011. However, NLEM, 2015 came into force vide DoP notification SO 701(E), issued on 10th March, 2016, in which the formulations, **Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg and Erythromycin Syrup 125mg.5ml.**, were shifted to non-scheduled category.

5.2 The review order No. 31015/20/2015-PI.I, dated 30th August, 2016, was issued by DoP, to settle the grievances raised by M/s IPCA Laboratories Ltd. against the ceiling prices fixed for **Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg, Erythromycin Syrup 125mg.5ml. and Chloroquine Phosphate Injection 40mg/ml** by NPPA vide SO 834(E), dated 25.3.2015. At that time, the aforesaid formulations were scheduled medicines. However, by the time the Review Order was issued (on 30.8.2016), out of four medicines, three medicines, viz. **Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg and Erythromycin Syrup 125mg.5ml.**, have been shifted to non-scheduled category. Only one formulation Chloroquine Phosphate Injection 40mg/ml is left in the category of scheduled medicines (at 6.5.3.1 in Schedule-I of NLEM,2015). Fixation of ceiling prices of non-scheduled formulations is contrary to the provisions of DPCO, 2013. In view of this, NPPA may be directed to issue revised SO by excluding the formulations **Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg and Erythromycin Syrup 125mg.5ml.**, which have since been shifted to non-scheduled category under Schedule-I of NLEM, 2015, and revising the ceiling price of only one formulation, viz. Chloroquine Phosphate Injection 40mg/ml.

6. Government Decision:

“NPPA is hereby directed to issue revised SO within one month by excluding the formulations Erythromycin Estolate Tablets 250mg, Erythromycin Tablets 500mg and Erythromycin Syrup 125mg.5ml., which have since been shifted to non-scheduled category under Schedule-I of NLEM, 2015, and re-fixing the ceiling price of only one formulation, viz. Chloroquine Phosphate Injection 40mg/ml.”

Issued on this date, the 24th day of August, 2017.

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

To

1. M/s Alembic Pharmaceuticals Limited,
Prithvi Mansion, 4/8, Asaf Ali Road,
New Delhi-110002.
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